Comparative costs and cost-effectiveness research on materials and approaches in the treatment and prevention of dental caries in a mixed dentition: Community trials in Wuhan, China and Paranoá, Brazil

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Dedicated to the memory of my parents
and to my husband, Joe.

Comparative costs and cost-effectiveness of materials and approaches in the treatment and prevention of dental caries in a mixed dentition: Community trials in Wuhan, China and Paranoá, Brazil

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Doctoral Thesis

to obtain the degree of doctor

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on the authority of the Rector Magnificus prof. dr. J.H.J.M. van Krieken,
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by

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Original Publications

This PhD thesis was based upon the following original publications:

Goldman AS, Chen X, Fan M, Frencken JE. Methods and preliminary findings of a cost-effectiveness study of glass-ionomer-based and composite resin sealant materials after 2 years. *Eur J Oral Sci* 2014; 122: 230–237.

Goldman AS, Chen X, Fan M, Frencken JE. Cost-effectiveness, in a randomized trial, of glass-ionomer-based and resin sealant materials after 4years. *Eur J Oral Sci* 2016; 124: 472–479.

Goldman AS, Leal SC, de Amorim RG, Frencken JE. Treating high-caries risk occlusal surfaces in first permanent molars through sealants and supervised toothbrushing: A 3-year cost-effective analysis. *Caries Res* 2017; 51: 489–499.

Goldman AS, de Amorim RG, Frencken JE, Leal SC. Replacing amalgam with a high-viscosity glass-ionomer in restoring primary teeth: A cost-effectiveness study in Brasilia, Brazil. *J Dent* 2018; 70: 80-86.

Chapter 1

Introduction, rationale, and aims of the research

Introduction

Dental caries: burden of disease and economic implications

Dental caries prevention is a strategic priority in WHO's global disease prevention framework. According to WHO data, 60–90% of schoolchildren and nearly 100% of adults have dental cavities often leading to pain and discomfort (1). Untreated caries was the most prevalent condition among 291 studied in the 2010 Global Burden of Disease study, affecting 2.5 billion people (2). Untreated caries in the deciduous dentition was the 10th most prevalent condition worldwide, affecting 9% of the global population.

Listl and colleagues (3) estimated the global economic impact of dental diseases worldwide. Annual direct treatment costs were estimated (in 2010 values) at $298 billion per year while indirect costs (productivity losses) were estimated at $144 billion per year (3). These estimates, which project the estimated annual costs of 187 countries, drew on available data from 66 countries.

The large burden of untreated caries, particularly among schoolchildren, the high costs of restoration, and the importance of safeguarding oral health during critical years of oral cavity development point to the need for population-based cost-effective preventive solutions. This is true of low-income countries as well as countries that have experienced high growth.

Economic growth, health and oral health in China and Brazil

Technological and scientific advances, increased globalization, and economic growth have brought about great change in developing economies and their health systems, which have brought about improvements in life expectancy and living conditions for large segments of the world's populations.

Nonetheless, conditions of poverty and ill health persist in populations around the world and the ability of national health systems to reach their populations is uneven in terms of service provision and access, resulting in health inequalities. Oral health promotion services have tended to lag far behind other health services because historically the oral health professions and services have developed separately from other curative health disciplines. And frequently,

the traditional structure of oral health services provision has been one whereby these services are not covered by the state.

This is particularly true in countries where the economies have been developing rapidly since the end of the 20th century such as China and Brazil. Both countries have experienced large income and health related inequalities, which persist, affecting the poorest sectors of their populations (4, 5).

Between 1990 and 2010, China experienced 300% income growth. In that same period income inequality grew substantially — its Gini coefficient increased from 32.7 to 47.8. In Brazil, income inequality dropped from 60.4 to 52.7, but despite this drop, income inequalities persisted (4). During this period, both countries have worked toward expanding the coverage of their health systems. China promoted universal maternal and child health care. Brazil implemented policies of economic redistribution and sought to expand universal health care. Curative oral health services grew in both countries, primarily in the private sector in large urban areas, meaning access was difficult because private oral health care tends to be very expensive and public oral health services were not expanding rapidly enough to meet the needs of the populations.

The result is that often people seeking oral health care would have to pay out of pocket and it has been demonstrated that these out of pocket payments can become catastrophic in nature if they exceed 40% of household income (6). In a global study of catastrophic dental health expenditures, in low and middle income countries (using data from the World Health Survey 2002–2004), people were asked whether they had had dental health expenditures in the last four weeks. In Brazil for 25.3% of the households that incurred dental expenditures (within the last four weeks), those expenditures were catastrophic; in China, 13.3% of households that spent money on dental care experienced catastrophic expenditures (6).

A review of surveys of the prevalence of early childhood caries in mainland China showed an overall pooled prevalence of caries of 65.5% between 1987 and 2013 in children between the ages of 1 and 6 years of age; with 6-year-olds at the highest level of prevalence, 70.7%. Studies since 2010 report a pooled caries prevalence of 56.4%. Children in rural areas were at a higher risk of developing caries. While treatment of the deciduous teeth tends to be low in general, children in rural areas are less likely to receive care (7).

Data from within the last decade show that although oral health indicators have improved in Brazil they have done so on a social gradient. In a study comparing data from the Brazilian National Health Surveys in 2003 and 2010, Roncalli *et al.* (8) demonstrated that although the country experienced an "overall reduction in DMFT as well as an increase in caries free individuals, there were increases in both income and education-related inequalities" while for other health conditions there had been reductions in inequalities.

Economic evaluation of oral health interventions

A study of the burden of disease of dental caries in children by Yee and Sheiham (9) found that more than 90% of the dental caries in developing countries remained untreated. They estimated that the restoration of the permanent dentition of the child population of low-income nations using traditional amalgam restorative dentistry was beyond the financial capabilities of 15 to 29 of the 45 low-income countries studied.

In countries faced with inequitable distribution of health resources leading to disparities in health outcomes, the challenge is to develop intervention strategies that serve to maximize the use of available local resources. Policymakers and program directors need information about the effectiveness of current and proposed programs, and whether these are politically acceptable, technically feasible, and affordable.

Economic evaluation adds an important dimension to decisions about competing health interventions and limited resources. It can provide information for the advocacy of oral health programs, as well as for new health interventions or technologies (10). In addition, economic evaluation provides basic information about the resources needed to start or expand projects (10).

Rationale

Dental caries prevention

As children grow, they undergo a number of natural processes including the maturation of the oral cavity. At around age 6 they begin to shed the incisor primary teeth and the permanent

teeth begin to grow in. When dental caries develops, the natural processes in the mouth are disrupted by disease and tooth loss.

Dental caries is a preventable disease. Primary preventive approaches through oral health education program regarding diet modification to reduce sugar intake, oral hygiene through the daily removal of biofilm from tooth surfaces with toothbrush and fluoridated toothpaste are the principal measures that curb dentine carious lesion development (1, 11). Lack of compliance, willingly, or unwillingly, is a major barrier to success.

Dental practitioners worldwide have advocated and implemented intervention strategies that serve to enhance the ability of existing primary oral health education initiatives to prevent the development of dental caries in children. Sealing the pits and fissures in the first permanent molars of high caries risk young children is one such intervention preventive approach which employs resin- and glass-ionomer-based materials for sealing the pits and fissures of the permanent molars.

In a systematic review comparing resin- and glass-ionomer-based materials with improved characteristics, Mickenautsch and Yengopal (12) found that the caries-preventive effects of these materials are similar. This was confirmed most recently by Wright and colleagues (13).

In the case of cavitated dentine carious lesions in the primary teeth, early detection and appropriate intervention is necessary to promote normal exfoliation and thereby minimizing possible functional and alignment effects in the permanent dentition (14). The traditional approach to treating cavities in the primary teeth has been to restore them with rotary instruments and amalgam, and in recent years, with composite resin. Atraumatic restorative treatment (ART) is a minimal intervention approach well accepted among children, which produces restorations similar in quality to amalgam, in both the primary and permanent teeth, and to composite resin in primary teeth (15), using hand instruments and high-viscosity glass-ionomer cement.

Other alternatives are emerging such as sealing in carious lesions in the primary teeth with a prefabricated crown (16) or widening cavities to allow cavity cleaning in conjunction with the application of fluoride varnish or a glass-ionomer cement liner (17). The evidence for the effectiveness of these alternatives is still weak.

Within the last decade, two retrospective studies (18, 19) and one (20) prospective study reported that approximately 18% of the teeth with open cavities did not have a good exfoliation outcome. These results prompted the idea of an alternative to safeguard the exfoliation of cavitated primary teeth without symptoms via a combination of the ART approach using high-viscosity glass-ionomer cement (HVGIC) to restore small cavities and daily plaque removal with toothbrush and toothpaste from medium and large-sized cavities (21).

Research on the effectiveness of a variety of dental restorative materials is ongoing with a focus on the prospects of the phase out of amalgam. In a systematic review and meta-analysis of studies of HVGIC and amalgam restorations, Mickenautsch and Yengopal (22–23) found no difference in the effectiveness of the two materials in terms of survival of the restorations. To date there are no direct comparisons of failure rates between conventional high-viscosity glass-ionomer restorations direct hybrid resin composite restorations in patients with single and/or multiple-surface cavities in posterior permanent teeth (24).

Research on cost-effectiveness of caries preventive strategies

As outlined above, a considerable amount of research on the effectiveness of sealants in preventing caries lesion development has been conducted. There is very little research in terms of economic evaluations of sealants. Authors of recent reviews in this area have found few articles and these are of variable quality (25–27).

With respect to the comparable cost-effectiveness of HVGIC and amalgam or other restorative materials, to date only one recent study has been identified by da Mata *et al*., (28), a clinical trial evaluating the cost-effectiveness of ART/HVGIC compared to conventional treatment with resin-modified glass ionomers in elderly adults which found the ART/HVGIC treatment more cost-effective after one year. There are no studies evaluating the cost-effectiveness of different restoration approaches and materials for pediatric patients. Research in this area is warranted.

Another area where more research is needed is the estimation of any potential additional costs associated with making the change from amalgam to other restoration materials. A search of the literature for studies that have investigated this particular topic in the primary

dentition did not yield any peer review articles.

Data on costs and cost-effectiveness of oral health interventions are part of the constellation of factors that should be considered in the planning, development and implementation of oral health policies, programs and services. Other factors include health conditions, finances, equity and distributional aspects (29), including the extent and modalities of services, and their accessibility for the population, particularly the poor, and levels of education and knowledge among the population as well as caregivers and health promoters.

Primary aims of the PhD research

The primary aims of this PhD thesis are to investigate and compare the costs and cost-effectiveness of various oral health primary care intervention and prevention strategies adopted in the prevention and treatment of dental caries in 6 to 8-year-old children in China and Brazil.

The studies in this PhD thesis take the perspective of government oral health programs designed for delivery through the public-school system in countries where oral health services are still not fully articulated. Its aim is to provide information about the cost-effectiveness of the programs, the costs of all inputs, and the potential implications of their delivery to underserved populations. The work here is informed by work experience in cost analyses of community-based programs to prevent lymphatic filariasis, including the design, implementation, and analysis of protocols for cost data collection for a series of integrated neglected tropical disease programs.

In Wuhan, China, Chen *et al.* (30) conducted a randomized community effectiveness study that investigated the caries preventive effects of glass-carbomer in comparison with HVGIC, with and without heat application, and composite resin after 2 years and again after 4 years.

The Brazil studies formed part of a community randomized trial, which evaluated the effectiveness of three treatment approaches to promote natural exfoliation of the primary dentition (21) including supervised toothbrushing of open cavities in the primary molars, care of the primary dentition in the form of restorations (31), as well as prevention of dentine carious lesions in the first permanent molars through sealants and supervised toothbrushing (32). The three approaches were: (i) conservative restorative treatment (CRT), which used amalgam for

restorations of the primary dentition and composite resin sealants for the permanent molars, excavated and applied with rotary instruments; (ii) atraumatic restorative treatment (ART), which used high-viscosity glass-ionomers to restore the primary molars and seal permanent molars via excavation and application with hand instruments; and (iii) ultra-conservative treatment (UCT), wherein some primary molars were restored with high-viscosity glass ionomers and others with large cavitated dentine lesions were cleaned daily with toothpaste and a toothbrush under supervision. First permanent molars were also brushed daily under supervision.

The cost data used in this thesis were obtained prospectively. Inputs, purchased or donated, were costed — personnel, instruments and supplies, transportation, and capital equipment — and entered in Excel spreadsheets. These were fed into a model that took into account the numbers of interventions performed and adverse events such as the development of secondary dentine-carious lesions and extractions. The costs to perform sealants, restorations, and of supervised toothbrushing were estimated. Costs and outcomes were discounted and to produce a net cost per sealant or per restoration. When appropriate, incremental cost-effectiveness ratios were employed to compare the different approaches (29, 33). The incremental cost-effectiveness ratio (ICER) is a measure that serves to predict the cost associated with preventing each additional adverse outcome. It provides a measure of the cost per unit of effectiveness for each of the different alternative primary care intervention strategies.

The specific aims for the China study are:

1. To calculate the cost to perform and the net cost per sealant in the four study groups.
2. To evaluate the incremental cost-effectiveness of the sealants in preventing carious lesions given their rates of survival, 2 and 4 years after placement.

The following are the specific aims for the Brazil studies:

1. (a) To calculate the cost to perform and the net cost per composite resin and ART/HVGIC sealant and the cost and net cost per caries free occlusal surface in the supervised tooth brushing group after 3 years; and

   (b) To determine the incremental cost-effectiveness of the two sealant types compared to supervised tooth brushing given their rates of prevention of dentine carious lesions after 3 years.

2. To evaluate the costs and outcomes of two approaches, the Conservative Restorative Treatment (CRT) which uses amalgam, and Atraumatic Restorative Treatment (ART) which uses high-viscosity glass-ionomer (HVGIC), in caring for the primary molars by
   (a) determining the mean time spent, for each intervention protocol, in carrying out single- or multiple-surface restorations;
   (b) assessing the costs and net costs associated with the placement of restorations for each intervention protocol — amalgam and ART/high-viscosity glass-ionomer (ART/HVGIC);
   (c) conducting a cost-effectiveness analysis of comparing amalgam to high-viscosity glass-ionomer (HVGIC) as a restoration intervention practice and evaluate; and
   (d) determining how changes in cost inputs for each method affect the cost of the restorations and the cost-difference of switching from amalgam to high-viscosity glass-ionomer.

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Chapter 2

Methods and preliminary findings of a cost-effectiveness study of glass-ionomer-based and composite resin sealant materials after 2 years

This chapter was published as Goldman AS, Chen X, Fan M, Frencken JE. Methods and preliminary findings of a cost-effectiveness study of glass-ionomer-based and composite resin sealant materials after 2 years. *Eur J Oral Sci* 2014; 122: 230–237.

Abstract

The cost-effectiveness of glass-carbomer, conventional high-viscosity glass-ionomer cement (HVGIC) [without or with heat (light-emitting diode (LED) thermocuring) application], and composite resin sealants were compared after 2 years in function. Estimated net costs per sealant were obtained from data on personnel time (measured with activity sampling), transportation, materials, instruments and equipment, and restoration costs for replacing failed sealants from a community trial involving 7–9-year-old Chinese children. Cost data were standardized to reflect the placement of 1,000 sealants per group. Effectiveness outcomes were the differences in the number of dentine caries lesions that developed between groups. The average sealant application time ranged from 5.40 minutes (for composite resin) to 8.09 minutes (for LED thermocured HVGIC), and the average cost per sealant for 1,000 performed per group (projection) ranged from US$3.73 (for composite resin) to US$7.50 (for glass-carbomer). The incremental cost-effectiveness of LED thermocured HVGIC to prevent one additional caries lesion per 1,000 sealants performed was US$1,106 compared with composite resin. Sensitivity analyses showed that differences in the cost of materials across groups had minimal impact on the overall cost. Cost and effectiveness data enhance policy-makers' ability to address issues of availability, access, and compliance associated with poor oral-health outcomes, particularly when large numbers of children are excluded from care, in economies where oral health services are still developing.

Introduction

Untreated caries was the most prevalent condition among 291 studied in the 2010 Global Burden of Disease study (1, 2). Between 1990 and 2010, the disability adjusted life years (DALYs) per capita for all oral health conditions, predominantly untreated caries, severe periodontitis, and severe tooth loss (or edentulism), decreased from 242 to 224 DALYs per 100,000 population. Edentulism decreased by 39.8%. Nonetheless, in contrast to a downward trend for DALYs per capita for all health conditions studied since 1990 (a 23% decrease), untreated caries and periodontal conditions have increased by 3.2% and 11.3%, respectively. For untreated dental caries in permanent teeth, the loss of DALYs per capita is 73 per 100,000 population (1). In East Asia, one of two regions in the world where there has been an increase in the number of DALYs as a result of a decrease in oral health conditions, the health loss is estimated at 222 DALYs per 100,000 persons (1).

Dental caries is a preventable disease, and various preventive methods are available. Sealing the pits and fissures in the first permanent molars of caries-high-risk young children is considered as the most effective method to prevent carious lesions during the critical early years of the development of molars. However, sealants can fail, and such an event requires regular access to dental health services. In low-income and emerging-market economies, the oral health systems may not yet be sufficiently organized to address this need. In China, for example, the molars of schoolchildren are treated with sealants and the children are given instructions on oral health care, thereby providing them with the opportunity to preserve their molars. Under these conditions sealant materials with the capacity to create a longer-lasting bond with the enamel surface are essential (3).

The materials used for sealing pits and fissures have traditionally been resin- and glass-ionomer-based. Glass ionomers bond chemically to the tooth tissues, leach fluoride onto the enamel and dentine, and are easily applied in non-clinical settings. Recent systematic reviews (4, 5), comparing resin- and glass-ionomer-based sealant materials with improved characteristics, have demonstrated that the caries-preventive effect of these materials are similar. Glass ionomers are constantly being improved. For example, since the mid-1990s, the glass ionomers used in sealants, applied using the atraumatic restorative treatment (ART) approach,

have been of a high-viscosity type. Around 2005, a high-viscosity glass-ionomer cement (HGVIC), with an elevated powder : liquid ratio and claiming stronger adhesion to enamel than previous glass ionomer materials, appeared on the market (6). The application of heat with a high-intensity curing light was found to increase the retention of the glass-ionomer material to enamel (7). In 2007, a new glass-ionomer-based material with powder-based particles reduced to nanosize and containing fluorapatite, termed glass-carbomer, became commercially available.

While a considerable amount of research has been conducted on the effectiveness of sealants in preventing caries lesion development, there is a paucity of economic evaluations of sealants, and no economic evaluations of the efficacy of sealant materials have been identified in the English language literature. A systematic review, by Källestål *et al.* (8), of studies spanning the period 1966–2003, found only 17 original studies out of 74 journal articles that discussed the economic evaluation of caries prevention.The articles covered a range of approaches to caries lesion prevention, including fluoride rinses, fluoride varnish, and whole preventive programs. Four dealt with sealants, and the authors concluded that the evidence was of low value and questionable in terms of cost-effectiveness.

Development of the new glass-carbomer and the glass-ionomer with an elevated powder : liquid ratio prompted Chen *et al.* (3) to design a randomized community-effectiveness study to investigate the caries-preventive effects of glass-carbomer in comparison with HVGIC, with and without heat application, and composite resin after 2 years in function and again after 4 and 6 years in function (3).

A cost-effectiveness analysis was conducted prospectively as part of the sealant community trial of Chen *et al.* (3), with the following objectives: (i) to calculate the cost and net cost per sealant in the four study groups 2 years after placement; and (ii) to determine the incremental cost-effectiveness of the sealants given their rates of survival 2, 4, and 6 years after placement. In addition, this report aimed to outline the methods used to obtain and analyze the cost-related data in detail, as a basis for future reports.

Material and methods

Study population and procedures

The community trial was conducted in Wuhan, China. The study was approved by the Research Ethics Committee of the University of Wuhan (no. 200704) and was registered at the Dutch Trial Registration Centre (no. 1441). The sample was nested in an oral epidemiological survey of schoolchildren, average age 8 years (9). Caries lesions were assessed using the ART criteria (consisting of the numbers of enamel and dentine lesions, and of missed and filled teeth) (3) as well as the criteria of Symons *et al.* (10), for evaluating the morphology of pits and fissures in the first permanent molars. Inclusion criteria were: at least one fully erupted first permanent molar; no dentine-caries lesions in the pits and fissures of these molars; deep and/ or intermediate pits and fissures; a mean decayed, missing, and filled teeth (dmft) score of ≥2; and a consent form signed by parents. Previous research in Wuhan had shown that permanent first molars with enamel caries lesions, and those with dentine caries lesions in primary teeth, were powerful predictors of dentine caries lesion development over a 4-year period in a similar age group (11).

Children were assigned to one of four treatment groups using a list obtained after block randomization. The groups were: elevated powder: liquid ratio HVGIC (Ketac Molar Easymix; 3M ESPE, Seefeld, Germany); light-emitting diode (LED) thermocured HVGIC (Ketac Molar Easymix cured with an 850 mW/cm^2 intensity LED light) (Elipar Freelight; 3M ESPE); glass-carbomer, LED cured (First Scientific Dental, Elmshorn, Germany); and composite resin (Clinpro; 3M ESPE), also LED cured. Composite resin was considered the standard of care and therefore was the control group.

The intervention consisted of a single application of sealants in the pits and fissures of occlusal surfaces as well as in those of buccal and palatal (smooth) surfaces. The principal differences between the groups were as follows. For the three glass-ionomer-based material groups, operators used hand instruments only, following the ART approach (12); a portable dental unit and related instruments were used for the composite resin group; and an LED

light was used to heat-cure sealants in one of the high-viscosity glass-ionomer groups, as well as in the glass-carbomer and the composite resin groups (3).

Three operators and two assistants carried out the treatment sessions in the schools over a period of 2 months. As the procedure of placing glass-ionomer and glass-carbomer sealants was new to the dentists and assistants, and as resin-composite sealants had been very rarely used by two of the three operators, a 4-week laboratory and field training program was carried out. Selection bias was controlled by having the block randomization performed by an outside expert and by keeping the list concealed from the operators until the time when the treatment started. Children were considered blinded to the procedure. For many children, this was the first treatment they had ever received. Blinding of the statistician was achieved by assigning numeric codes in lieu of group names. These were decoded only at the end of the analyses. Operators could not be blinded, but almost all procedures were new to the three operators, so prior preference for a certain procedure was very unlikely. For more details about the sealant study, the reader is referred to Chen *et al*. (3). Data on the number of children, the number of sealants, caries status, and survival rates, according to treatment group, are presented in Table 2.1.

Two calibrated and experienced independent evaluators, who were blinded to the sealant materials used, conducted evaluations at 6 months, and at 1 and 2 years. Although examiners were not informed about the materials applied, it is possible that they noticed a difference between the composite resin and the other three materials, which are similar. A dentine caries lesion was recorded if the enamel surface was cavitated and the caries lesion was judged to have involved the dentine. The kappa-coefficient value for intra-evaluator consistency was 0.90 for both evaluators and 0.63 for the inter-evaluator consistency.

Table 2.1: Intervention baseline characteristics and status at 2 years

Study time point/Variable	Treatment Group			
	HVGIC	LED thermo-cured HVGIC	Glass car-bomer	Composite resin
Baseline				
Children	97	104	98	108
Sealed pits and fissures	450	501	430	478
Occusal sealants	312	351	324	357
Free-smooth sealants	138	150	106	151
d_3mft	4.8±2.6	4.9±2.6	4.7±2.6	5.0±2.4
D_3MFT	0.1±0.4	0.2±0.4	0.1±0.3	0.1±0.4
Two years				
Children	89	98	91	102
Sealed pits and fissures	415	471	396	452
Dentine carious lesion increment	7	5	10	5
d_3mft	4.1±2.5	4.2±2.4	4.3±2.7	4.0±2.5
D_3MFT	0.3±0.7	0.3±0.6	0.3±0.7	0.2±0.6
Effectiveness	98.3%	99.0%	97.4%	98.9%

d_3mft, dentine carious lesions in the primary teeth; D_3MFT, dentine carious lesions in the permanent teeth. Values are given as n or mean ± SD, unless indicated otherwise. Data are given at baseline and at 2 years, according to treatment group, for the number of children, occlusal and free-smooth surface sealants (baseline only), sealed pits and fissures, d_3mft, D_3MFT, dentine carious lesions increment (2 years only) and effectiveness of caries prevention (2 years only).

Cost-effectiveness study design

The cost-effectiveness analysis was designed from the perspective of a government oral health program that would probably be implemented in schools and with government public health policymakers as the intended audience. The outcomes were the differences between the groups in the number of dentine caries lesions that developed after 2 years, and later, at 4 and 6 years, and the number of restorations or extractions. The market costs of restorations and extractions at the School and Hospital of Stomatology in Wuhan were used to estimate the cost of a restoration, which was US$23.11.

Cost data collection

The investigators obtained cost data from the records of study expenditures kept at the School and Hospital of Stomatology in Wuhan. Costs used to estimate the cost per sealant were personnel time, materials, instruments, and equipment required for sealant placement, as well as relevant operator transportation costs to and from the schools. Intervention cost data were collected prospectively in most instances. The financial costs presented here covered all the actual costs (cash disbursements) required to carry out the sealant intervention (13). Capital expenditures for equipment were annuitized at a rate of 3%.

A key element in cost is personnel time. In the present study, activity sampling (14) was used to measure personnel time through self-reporting by the dental assistant who helped the operating dentist.

The cost of a dental intervention includes personnel costs for treatment, as well as other activities. In this study, activities were categorized as follows: clinical activities (including examination and diagnosis, and sealant treatment), according to group; complementary activities, such as preparation of the treatment area and awaiting patients; and other activities, which included captured downtime owing to patient or operator absence or equipment failure. Operators and assistants were instructed to practice activity sampling data collection for 2 or 3 days at the start of the study. The sample size required to capture a representative sample of treatment sessions was estimated to be 19 days of treatment sessions (morning and afternoon). Eventually, activity sampling data were collected for 46 days of treatment (a total of 92 morning and afternoon sessions), which represented close to 80% of the treatment performed in the study.

Key activities were coded with a two-digit identifying number and samplings were made at 15-minute intervals using a countdown timer. To avoid bias caused by sampling exactly the same time intervals in each session, a different number was used to define the time interval before the countdown timer was turned on for the first time during the session. This number was given as the last digit of the first participant's identification number for each morning and afternoon session.

Data on sealant placement were also captured independently of activity sampling. The rationale for using both methods was to compare the two for accuracy of the recorded data. As part of the present study, the assistant recorded the start and the end of each sealant placement procedure. The start time was defined as beginning the moment the operator picked up the instruments and began the procedure; treatment ended after bite adjustment was completed and instruments were placed on the tray.

Data analysis

The baseline intervention lasted for about 2 months. Costs such as personnel and the annualized cost of equipment were apportioned to the project according to the percentage of a full time equivalent (FTE) these represented. Other costs, such as instruments and supplies, were apportioned to the group using that type of material. When the instruments and supplies were shared by more than one group, these were apportioned according to the number of groups sharing them and the number of sealants performed in each of those groups.

The cost to perform one sealant was calculated from the cost data by dividing the total expenditure for each group by the number of sealants performed for each group. It was also estimated by measuring the amount of personnel time devoted to each activity performed in the session and adding this to the per sealant costs of the other inputs involved in each session (i.e. instruments and supplies, equipment, transportation, and facilities).

Slight variation was observed in the numbers of children and of sealants in each study group. To present consistent estimates across the groups, the cost data were standardized to simulate the placement of 1,000 sealants in each group. Based on the 1,859 sealants produced over a 2-month period for this study, it was estimated that it would take 4.3 months to apply 1,000 sealants in each group. This meant that the proportions of personnel time, use of equipment and instruments, and the increase in material costs were increased to reflect the increase in the number of sealants performed. The increase was made under the assumption that the consumption rates of all inputs remained the same. The study's effectiveness result was applied to the projection.

Personnel time measurement

SAS version 9.3 (SAS, Cary, NC, USA) was used to calculate mean values and SD for personnel time using two types of data: the actual mean treatment time per sealant; and the mean treatment time estimated with the activity sampling data. The time estimates (minutes) per sealant for both data sets were summarized with means. These were compared for each data set using the GLM procedure, which uses the method of least squares to fit general linear models and Duncan's multiple range test.

Outliers were evaluated in both the treatment and activity sampling data sets, using PROC UNIVARIATE, a SAS procedure that produces statistics describing the distribution of a single variable. For the activity sampling data, six sessions with extreme values were excluded. In the case of the sealant placement time from the treatment data set, extreme values were identified according to tooth, and 13 were excluded.

Costs and cost-effectiveness

The sealant performance costs were combined to estimate the cost and to evaluate the cost-effectiveness of each material and approach used in their application. The average cost per sealant was derived by dividing the net costs for each group by the total number of sealants performed. Net costs are defined as the costs of the intervention with each type of material plus the costs of the adverse effects (failed sealants) of the intervention (13). The groups were compared in an incremental analysis to evaluate their efficiency (13). The incremental cost-effectiveness ratio (ICER) (Eqn 1, below) is the difference between net intervention costs for one of the glass ionomer groups (e.g. LED thermocured HVGIC) (GI) and the net costs for the composite resin group (CR) (i.e. the net costs of the standard of care) in the numerator; the denominator consists of the difference between the caries outcome for LED thermocured HVGIC and that of the composite resin group.

Equation 1

$$\text{Incremental CEA} = (\text{Net Cost GI}—\text{Net Cost CR})/(\text{Outcome CR}—\text{Outcome GI})$$

Sensitivity analysis

Sensitivity analyses were conducted to assess the impact of varying the values of certain inputs on the net cost of performing one sealant. One-way analyses were performed on personnel and equipment; and on instruments and supplies (range: 3–15% increase). The effect of dentine caries lesion incidence on the ICER was also examined.

Currency, exchange rates, and discounting

The majority of cost data were collected in Yuan in 2008. In some cases cost data were obtained in 2010 Euros or US dollars and converted to 2008 Yuan (15). All costs were adjusted for inflation and converted to 2010 US dollars for reporting in this article using the gross domestic product (GDP) deflator from The World Bank World Development Indicators database (15). All costs are reported in US dollars. Costs and effects were not discounted because of the short time frame and the small number of outcomes (resulting in dentine caries lesions).

Results

Time measurement

On average, operators spent 119 minutes performing clinical activities in each session (Table 2.2). The difference in the mean lengths of the morning (198 minutes) and afternoon (163 minutes) sessions was statistically significant ($P < 0.0001$).

The mean treatment times and SDs estimated from the activity sampling data ranged from 5.40 minutes for the composite resin to 8.09 minutes for the LED-cured HVGIC group (Table 2.3). The mean treatment times estimated for the three glass-ionomer-based groups were not significantly different from one another, whereas the difference between all three and the composite resin group was statistically significant for the LED thermocured HVGIC and glass-carbomer groups ($P < 0.0001$), and for HVGIC ($P = 0.0013$).

Table 2.3 also shows the mean treatment times and SD for occlusal and smooth sealants obtained from the treatment data set. The mean occlusal treatment time ranged from 6.03 minutes for the composite resin to 9.20 minutes for the glass-carbomer sealants; smooth sur face sealants took less time, ranging from 3.67 to 6.48 minutes, respectively. The mean treatment times for occlusal sealants for the LED thermocured HVGIC and glass-carbomer groups did not differ statistically but were significantly different ($P < 0.05$) from the means for the other groups, which were also significantly different from one another. The mean times for the smooth surface sealants were all significantly different from one another.

Sealant costs

The cost of performing one sealant per group for the study sample ranged from US$3.05 for composite resin to US$7.84 for glass-carbomer (Table 2.3). For the projection, the cost of composite resin was lowest, at US$3.47, and that of glass-carbomer was highest, at US$6.89. Costs in the projection were somewhat lower than in the study sample for the three glass-ionomer-based materials but not for composite resin, which was somewhat higher.

Table 2.2: Session measurement: activity sampling data

Variable	Duration (min)	%*
Session (n = 86)†	180 ± 32.2	
Clinical activities	119 ± 35.4	66
Complementary activities	28 ± 2.5	15
Other activities	45 ± 21.3	25

Values are given as mean ± SD. *Percentage of the session represented in that category. Note the proportions are averages and therefore do not sum to exactly 100%. †Activity sampling was carried out in a total of 92 sessions, which was reduced to 86 in the analysis after the exclusion of outliers.

Table 2.4 shows the actual and projection costs according to input and treatment group. The highest costs for the three glass-ionomer-based groups were incurred in instruments and supplies, particularly the sealant materials (87%), whereas a negligible amount (2%) was spent on equipment. In the compo-site resin group, instruments and materials amounted to about 56% of its resources, while equipment ac-counted for 13%. For the actual study sample, the largest percentage of costs was for instruments and supplies for all four groups, followed by personnel. In the projection of 1,000 sealants per group, the percentage of costs for instruments and supplies begins to decrease, while the percentage of costs for personnel begins to increase.

Table 2.3: Time and costs to perform sealants according to treatment group

Variable	Treatment group			
	HVGIC	LED thermocured HVGIC	Glass carbomer	Composite resin
Mean treatment time per sealant (min)*				
Activity sampling				
All	7.21 ± 2.39	8.09 ± 2.62	7.95 ± 3.04	5.40 ± 2.72
Treatment				
Occlusal	7.42 ± 1.96	9.08 ± 2.19	9.20 ± 2.36	6.03 ± 2.04
Free-smooth surface	4.73 ± 1.14	6.11 ± 1.16	6.48 ± 1.15	3.67 ± 1.05
Cost for performing one sealant ($US 2010)†				
Actual	4.57	4.65	7.84	3.05
Projection (1000 sealants/group)	4.04	4.65	6.89	3.47
Net cost per sealant ($US 2010)‡				
Actual	4.94	4.89	8.39	3.30
Projection (1000 sealants/group)	4.47	4.83	7.50	3.73

*Values are given in min ± SD per sealant. †Estimated from the actual study cost data and the projection of 1,000 sealants performed. des placement costs and restoration costs for surfaces that developed carious lesions.

Table 2.3 shows the net cost per sealant, which includes the costs of performing a sealant plus the net costs of addressing the adverse effects of the interventions. The net cost estimates from the actual study costs were US$3.30 for a composite resin and US$8.39 for a glass-carbomer sealant. In the projection, the composite resin sealant, at US$3.73, had the lowest net cost whereas the glass-carbomer sealant, at US$7.50, had the highest average cost.

Table 2.4: Program Costs

	Treatment group							
	HVGIC		LED thermocured HVGIC		Glass carbomer		Composite resin	
Variable	**Actual**	**Proj.**	**Actual**	**Proj.**	**Actual**	**Proj.**	**Actual**	**Proj.**
Personnel (%*)	309 (15)	1057 (26)	344 (15)	1176 (26)	295 (9)	1010 (15)	328 (23)	1122 (32)
Instruments/ supplies (%*)	1635 (79)	2746 (68)	1816 (78)	3052 (66)	2929 (87)	5562 (81)	824 (56)	1685 (49)
Equipment (%*)	0 (0)	0 (0)	46 (2)	100 (2)	40 (1)	85 (1)	187 (13)	403 (12)
Transportation (%*)	55 (3)	119 (3)	62 (3)	133 (3)	53 (2)	114 (2)	59 (4)	126 (4)
Facilities (%*)	57 (3)	122 (3)	63 (3)	136 (3)	54 (2)	117 (2)	60 (4)	130 (4)
Total cost	**2056**	**4044**	**2331**	**4597**	**3371**	**6888**	**1458**	**3466**

Data on total costs and individual costs for personnel, instruments/supplies, equipment, transportation, and facilities are reported in US$ 2010 for the actual sample and projection (Proj.) (1000 sealants per group), according to input and treatment group. *Expressed as a percentage of the total cost.

Cost-effectiveness

The incremental analysis in Table 2.5 shows that the glass carbomer is the most expensive and least effective of the four materials. HVGIC is less expensive and less effective than the LED thermo-cured HVGIC and the composite resin. These two groups are dominated by the other two. The caries-preventive effects of both the LED thermocured HVGIC and the composite resin groups were high, at 99% and 98.9%, respectively. The composite resin sealant costs less; however, it results in the development of one more dentine-caries lesion than the LED thermo-cured HVGIC group. The incremental difference between the two was US$1,106 for one additional dentine caries lesion prevented per 1,000 sealants placed.

Table 2.5: Incremental cost-effectiveness *(US$ 2010) per 1,000 sealed surfaces (projection) after 2 years according to treatment group

Intervention/ treatment group	Cost	Effectiveness (new dentine carious lesions)	Incremental Cost	Incremental effectiveness (new dentine carious lesions prevented)	Incremental cost per dentine carious lesion prevented
Glass carbomer	$7500	26			DOMINATED
HVGIC	$4445	17			DOMINATED
Composite resin	$3726	11	-$719	6	-$120
LED thermocured HVGIC	$4832	10	$1106	1	$1106

*The additional cost incurred by the next most effective strategy to produce an additional unit of the health outcome when strategies are ranked in order of effectiveness (13).

Sensitivity analyses

The sensitivity analyses showed that increasing the costs of inputs did not dramatically increase total costs. For instance, raising costs for instruments and supplies by up to 15% resulted in increases among the groups of 7–12%. For personnel, a similar increase made the costs for each group increase by 2–5%. Raising equipment costs had no effect on the overall costs for glass-ionomer-based groups, whereas the composite resin group's costs increased by 2%.

When caries dentine lesion incidence was increased by a factor of 5 for both the LED thermocured HVGIC and composite resin groups, the ICER decreased from US$1,106 to US$541, favoring the LED thermocured HVGIC group. An increase in incidence in the composite resin group, with no change in the LED thermocured HVGIC group, caused the ICER to drop to US$71 at 2.2% incidence and further to US$2 upon reaching 5%. Keeping incidence in the composite resin group constant, at 1.1%, whilst raising it in the LED thermocured HVGIC group, favored the composite resin ICER, showing savings of US$139 at 2%; however, the savings decreased to US$52 as carious lesion incidence in the LED thermocured HVGIC group reached 5%.

Discussion

The incremental cost-effectiveness ratio data show that the cost for the LED thermocured HVGIC group to prevent one more caries lesion for every 1,000 sealants placed is US$1,106 in comparison with the composite resin group. This amounts to a cost of US$1.11 more for each sealant placed with the LED thermocured HVGIC than for each composite resin sealant placed. Whilst cost-effectiveness is not the only factor to be taken into consideration when making decisions about implementing prevention programs, this result raises the question of whether or not the LED thermocured HVGIC intervention is acceptable or affordable, and what metric should be used to make that decision.

The determination of cost-effectiveness and acceptability relies on what Shillcut *et al.* (16) call the decision makers' valuation of a unit of health gain. In searching for a measure they examined several approaches to this problem. One approach was a standard cross-coun-

try threshold that emerged with the World Bank 1993 recommendation of a minimum care package of services for low- and middle-income countries. Interventions evaluated for that package, which cost US$150 (US$208 in 2008 values) per DALY, were considered to be within an affordable and acceptable range for low- and middle-income countries (16). The application of this measure to evaluate the sealant materials in this study would require adjusting the US$150 per DALY value to 2010 values; the result is US$226. If the burden of disease estimates for oral health conditions, and for dental caries specifically (1, 2), are adjusted for a population of 100,000, this translates into 2.2 DALYs per 10,000 persons and into 0.73 DALYs per 1,000 persons, respectively. In this study, 407 children had a total of 1,859 sealants, an average of close to 4.57 sealants per child. At that rate, the health loss for 1,000 children would be about 3.2 DALYs per 1,000 children, or 0.3% of one DALY per child. A cost of US$1,106 per caries lesion prevented, after the placement of 1,000 sealants, surpasses US$226 per DALY. This would be considered expensive in many countries, depending on their economic conditions and what they are willing to pay for this type of intervention.

The present study highlights a variety of factors that play an important role in deciding which sealant material is preferable. Key factors include program costs, conditions required for applying the material (e.g. a dental clinic, portable equipment, or a non-clinical space), equipment required, and the ability to reach a sizeable portion of the population. For instance, glass-ionomers have the advantages of portability and ease of use in clinical and non-clinical environments. In China, as in other nations relying on mobile care, these factors become important because children in such countries do not receive dental care as regularly as in other countries. One sealant application in the school setting will hopefully last until the child has managed to control dentine carious lesion development by him/herself. Under these conditions, some additional investment to provide children with sealants, which they might not obtain otherwise, may be worthwhile. Nonetheless, US$1,106 is very high, and, given the relatively low numbers of carious lesions overall, and in particular the very small difference between the LED thermocured HVGIC and the composite resin, this result should be viewed with caution.

Sensitivity analyses on the costs of inputs highlight group differences in terms of resource allocation, and, in particular, the costs of materials for the glass-ionomer-based groups, which

have implications for their cost-effectiveness and their affordability. The cost of labor was evaluated because this was the input that consumed the second-largest amount of resources. In addition, China's economy has grown rapidly in recent years, including labor costs, as evidenced by the rise in GDP per capita for Wuhan, which nearly doubled from US$2,480 in 2007 to US$4,428 in 2010. The sensitivity analyses evaluating the impact of incidence of dentine caries lesions on the ICERs for the LED thermocured HVGIC and composite resin groups revealed that the ICER was sensitive to changes in dentine caries incidence.

The finding that the two treatments produce a similar outcome means that the cost-effectiveness analysis can be reduced to cost minimization. However, this might be premature at this time because the investigators will perform follow-up evaluations. The investigators intend to continue to follow the children in this study for 6 years. The high success rate of the materials to date, and the need to follow the sealants for a longer period of time to see whether they fully accomplish their objective in preventing the development of dentine caries lesions over their expected 'life', make continuation of this study worthwhile.

One of the strengths of the present study is that it was designed to measure the costs and effectiveness of the sealant materials. After 2 years, all four groups had high rates of success in preventing the disease, demonstrating that both the glass-ionomer-based and composite resin materials are similarly effective in preventing dentine caries lesions.

In addition, the activity sampling data obtained to calculate the value of personnel time were collected for about 80% of the sample, more than the amount of data required to make representative estimates of personnel time. While it is possible that there could have been some recording errors, and bearing in mind that these are averages, the estimates of treatment time using the activity sampling data set were close to the actual sealant performance times, which were collected for the placement time of virtually the entire sample of sealants. Therefore, the two sets of estimates reinforce one another.

One of the study limitations may be that the application of the sealants in occlusal and free smooth surfaces were performed separately to ensure the highest quality in sealant placement and for consistency in treating and evaluating each sealant as a separate entity. Thus, because the dentists are working on research, the sealant placement times may be artificially high. The 2-year time-horizon for the cost-effectiveness results is short, making

the incremental cost-effectiveness ratio seem unacceptable, when it is possible that over time this ratio may improve.

Källestål *et al.* (8) found, in their 2003 review, few well-conducted studies with contradictory evidence in the reviewed articles, making it difficult to judge the health-economic effect of the caries-prevention methods studied. Based on this evidence, they concluded that fissure sealants are expensive unless only caries-active patients are treated. Ten years later, Mariño *et al.* (17) noted, in their systematic review of economic evaluations of dental caries prevention programs, that most of the articles in that review lacked the criteria for good quality studies and thus were not able to obtain a good measure of effectiveness and were forced to infer data. The present study has contributed to the cost-effectiveness evidence by producing cost estimates for glass-ionomer and composite resin materials.

Sealants can make a difference by preventing the development of caries lesions during a critical period for children who do not receive oral health care on a regular basis. This study highlights the factors that can assist policymakers in making decisions about how and what materials and approaches can be used to deploy viable prevention strategies under specific conditions.

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Chapter 3

Cost-effectiveness, in a randomized trial, of glass-ionomer-based and resin sealant materials after 4 years

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Abstract

This study, conducted from a government program perspective, compared the incremental cost-effectiveness of oral health interventions, in particular their delivery to underserved populations in whom dental sealants constitute an important, high-yielding complement to tooth brushing in dental caries prevention. The study data concern the relative cost-effectiveness of three sealant materials in four approaches to prevent cavitated dentine carious lesions in permanent molars in a community intervention trial among school-age children in Wuhan, China. The four approaches were high-viscosity glass-ionomer cement without heat application (HVGIC); high-viscosity glass-ionomer cement with heat application [light-emitting diode (LED) thermocured HVGIC]; glass-carbomer; and composite resin. The costs studied were: cost of sealing permanent molars; adverse event costs for restoring cavitated dentine carious lesions developing within 4 years in study data; and projection of 1,000 sealants per group. Preventing one more cavitated dentine carious lesion cost US$105 for the study data when comparing HVGIC (n = 405) with composite resin (n = 396) and US$59 per 1,000 sealants in the projections; LED thermocured HVGIC compared with composite resin cost US$115 for one more cavitated lesion and US$52 per 1,000 sealants, respectively. Although more expensive than composite resin, LED thermocured HVGIC was identified as the most cost-effective among the sealant materials studied. Ease of application, minimal technical and infrastructure requirements, and cost-effectiveness make glass-ionomers a practicable option for governments making decisions under economic constraints.

Introduction

The World Health Organization (WHO) decision to make dental caries prevention a strategic priority in global disease prevention (1) is strongly supported by the 2010 Global Burden of Disease (GBD) study finding that untreated dental caries in permanent teeth is the most prevalent condition among 291 diseases and injuries evaluated in the study. This 2010 GDB study ranked oral conditions among the 100 detailed causes of health status losses, summarized as disability-adjusted life years (DALYs) (2). Disability-adjusted life years, an internationally applied summary measure of population health by cause, combine years of life lost to premature mortality and years lived with disability (3). The concept of DALYs is helpful to nations in establishing health priorities and designing preventive and curative strategies to address them.

In countries in which the oral health infrastructure is still underdeveloped and not reliably accessible, oral health services often become the financial responsibility of individuals. Consequently, finding cost-effective ways to maximize the delivery of efficient and effective oral health prevention and curative services through government-sponsored programs continues to be of great importance to the goal of easing health burdens on human capital development in these countries. Social and economic policies in the BRICS countries — Brazil, the Russian Federation, India, China, and South Africa — have created substantial gross domestic product (GDP) growth since 1990, which coincides with sharply increasing inequality (4). Mujica *et al.* show that sizeable portions of the populations of some BRICS countries, specifically 47% in China, had incomes below the 50th percentile of the global income distribution in 2008, meaning that they fell within 50% of the world's poorest people (4). The GDP of China increased by 300% from 1990 to 2010. During the same period, losses of DALYs owing to dental caries increased, as did the average cost for typical out-of-pocket health expenditures. Both developments play a significant role for widening health inequalities and potentially undermine strategic efforts for sustainable GDP growth (5).

The 2010 GBD study reported that for the period 1990–2010 the DALY loss per 100,000 persons in the East Asia region increased from 207 to 222. China is the biggest country in the East Asia region (1) and, while it has grown rapidly in recent years, Chi-

na's health infrastructure is still not fully articulated to meet the current needs of the oral health sector (6). The inability to meet current oral health needs, combined with significant inequalities in the capacity to obtain oral health services, heightens the need for cost-effective oral-health prevention initiatives.

Interventions providing fluoride toothpaste and teaching children to care for their teeth by brushing regularly have become successfully established as workable approaches to preventing dental caries. Dental sealants have been shown to be a successful addition to tooth brushing in dental caries-prevention efforts, particularly when children's permanent molars begin to erupt and they are simultaneously being exposed to large amounts of caries lesions-inducing substances (7).

Research on dental materials and their sealant properties has shown high-viscosity glass-ionomer cements (HVGICs) to perform similarly to traditional composite resins in terms of durability (8–10). High-viscosity glass-ionomer cements can be applied in a variety of settings, including outside the dental clinic environment, and thus, can be used to reach underserved populations, including children in sparsely populated or remote areas. The process of applying heat to the setting phase of glass-ionomer cement has been demonstrated to increase its durability. Thermocuring glass ionomers with a high-intensity light-emitting diode (LED) lamp increases a sealant's mechanical-strength values (11). The potential societal benefits of these developments in materials science depend on their adoption by large numbers of practitioners. Nonetheless, more evidence is needed on the technical and economic viability of using LED thermocured HVGIC material for sealants in oral health-prevention programs. In 2007, another glass-ionomer-based material, known as glass-carbomer, emerged on the market. This material contains fluorapatite and is characterized by powder particles reduced to nanosize.

In efforts to identify cost-effective sealant interventions that reach larger portions of the population, the above-mentioned materials were assessed in a community trial implemented in 2008 in Wuhan, Hubei Province, China. The trial evaluated the costs of sealant placement on the first molars of schoolchildren and the cost-effectiveness of high-viscosity glass-ionomer cements, with and without heat application, glass-carbomer, and composite resin in preventing dentine carious lesions at 2 and 4 years after the intervention (12).

High-viscosity glass-ionomer materials were chosen for this study because research has shown that this type of sealant performs effectively when applied in environments outside the dental clinic, particularly in schools (8). It could thus contribute to a government oral health prevention program's capacity to meet the needs of larger numbers of children in the population because electricity is not required for placing these sealants and because in vitro tests have shown this material to have increased strength values (13). There was interest in the performance of the newly developed glass-carbomers under these conditions because the material contained fluorapatite and nanosized powder particles, which would increase sealant retention. Composite resin was chosen for the study because it is considered the standard of care in the placement of sealants in China and other countries; and, it is the approach that is commonly taught in China. Earlier research in young school-age children in Wuhan showed that 'enamel caries lesions in the first permanent molars and dentine caries lesions in the primary teeth' of 7- to 8-year-old children were predictive of dentine caries lesions over a period of 4 years' (14, 15). An epidemiologic study conducted before the community trial revealed dentine carious lesions in 8.7% of permanent teeth and in 68.7% of primary teeth of 6- to 7-year-old children; the prevalence of medium and deep pits and fissures was 84.6%, suggesting a potential value of sealants (16).

Sealants have an expected effective life of about 5 year and the investigators intended to follow them at 2, 4, and 6 years to see whether they accomplished their caries-prevention objective. However, for logistical reasons it was not possible to perform the 6-year evaluation. The 2-year evaluation results showed that all four materials were similarly successful and effective in their ability to prevent dentine carious lesions (12). At that time point, the costs per sealant placed for each group were calculated; the costs of restoring previously sealed surfaces where carious lesions had developed (adverse events) were added to the costs per sealant performed to estimate net costs. The differences between the net costs and outcomes for each group were calculated to provide a cost-effectiveness value. The result was inconclusive, largely owing to the relatively short period of time elapsed. This report used data collected from the clinical trial and projected data to present the cost-effectiveness results after 4 years, based upon the costs and survival and caries-preventive effects of the four sealant materials (14).

Materials and methods

The trial was approved by the Research Ethics Committee of the University of Wuhan (no. 200704) and was registered at the Netherlands Trial Registration Centre (no. 1441). Details of the study were published previously (12, 14) and a summary, covering elements such as population selection, types of sealants used, and the methods of their application, is provided below.

Study implementation

The community trial tested two hypotheses: (i) glass-carbomer sealants have greater cumulative survival rates and caries-preventive effects than the high-viscosity glass-ionomer sealants, with and without heat application, or the composite resin; and (ii) the LED thermocured high-viscosity glass-ionomer sealant has greater cumulative survival rates and caries (cavitated dentine carious lesions) preventive effects than does high-viscosity glass-ionomer sealant without heat application (12). The trial was implemented in five schools in Wuhan in the area where the aforementioned epidemiologic study (16) and the earlier research that was strongly predictive of the risk of dentine carious lesions (15) were carried out.

The study sample was chosen from schoolchildren, average age 8 years, evaluated in the epidemiologic survey in Wuhan (15). Study participants met the following selection criteria: at least one fully erupted first permanent molar; no cavitated dentine-caries lesions in pits and fissures of these molars; deep and/or intermediate pits and fissures; a mean decayed, missing, and filled primary teeth (dmft) score of ≥2 and; a consent form signed by parents (12). The following sealant groups were studied: elevated powder/liquid ratio HVGIC (Ketac Molar Easymix; 3M ESPE, Seefeld, Germany); LED thermocured HVGIC (Ketac Molar Easymix cured using an 850 mW/cm^2 intensity LED curing lamp (Elipar Freelight; 3M ESPE); glass-carbomer, LED cured (First Scientific Dental, Elmshorn, Germany); and composite resin (Clinpro; 3M ESPE), LED cured. Composite resin was considered as the standard of care and therefore was used in the control group (12).

An outside expert performed block randomization for group assignments; the list was concealed from the operators until the moment of treatment. Children were blinded as to the procedure performed in that the materials used were not discussed with them. Nonetheless,

for many this was the first time that they had received dental treatment so they were not aware that different techniques and approaches were used in the placement of sealants for study participants. Although operators could not be blinded, for most of them two of the procedures were new. For the analysis, the statistician was blinded to the groups and outcomes through coding (12).

The baseline intervention, a single application of sealants in the pits and fissures of occlusal surfaces and on buccal and palatial (smooth) surfaces, took place 6 months after the epidemiological survey was carried out. Sealant placement in the two high-viscosity glass-ionomer groups was performed using atraumatic restorative treatment (ART), which can be carried out outside the dental clinic environment. The glass-carbomer sealants were also placed using the press-finger technique, which is applied in ART but required a micro-motor and bur for finishing the sealant. The composite resin approach required more equipment — a dental unit (portable in this study) with a drill and other related instruments — and a clinical environment (12).

Over a period of 2 months, three operators and two assistants implemented the intervention, following a month-long laboratory and field training program for two of the operators because they did not have previous experience with the application procedure for glass-ionomer and glass-carbomer sealants (12). Children received emergency care at baseline and restorations when sealants failed and dentin caries lesions developed in the exposed pits and fissures. Sound teeth that lost sealant materials were not resealed (12, 17). The number of permanent first molars sealed was 1,304 in 215 boys and 190 girls; on average, 3.2 first permanent molars per child (17). Table 3.1 shows the data according to group.

The sealants were evaluated at 6 months and each year thereafter, for 4 years, by two calibrated and experienced independent evaluators, blinded to the sealant materials used, within the feasible bounds of technology and practice (14). The combined kappa-coefficients for inter-evaluator consistency for assessing caries lesions on tooth sections were 0.63 for the evaluations at 6 months, 1 year, and 2 years; and 0.83 for the 3- and 4-year evaluations.

Participants who developed dental caries received restorations on the previously sealed teeth. There were no patients in whom restorations failed and re-restoration was required in this study.

Cost-effectiveness study design and data collection

The cost-effectiveness study assumed the perspective of a government oral health services program for implementation in schools; its target audience being government oral health and education ministry managers and policymakers (14). The costs included were those costs that would be incurred by a government program to place the sealants in the schools and fill dentine carious lesions should these develop. Patient costs were not included in this study. The intervention was implemented over 2 months. The follow-up period and analytic horizon were 4 years; the cost-effectiveness analysis took into account all dentine carious lesions that developed over the 4 years.

The measure of effectiveness was the number of new cavitated dentine carious lesions that developed on the sealed tooth surfaces within 4 years of the intervention. Thus, study data measure the differences in the number of cavitated dentine carious lesions that developed and required restorations between the groups after 2 and 4 years.

In a cost-effectiveness study, the preventable costs (or adverse events costs) are those associated with the intervention. In this case, the restoration of dentine carious lesions that occurred as a result of unsuccessful sealants and the subsequent development of dentine carious lesions is considered a preventable cost. The costs for placing restorations were not measured in the community trial; thus, the amount charged at the School and Hospital of Stomatology in Wuhan (14), of US$23.11 per restoration, was used in this study.

Cost data used for this financial analysis were collected prospectively and analyzed in Microsoft Excel. The costs captured included the cost of personnel time, personnel transportation, materials, instruments, and equipment required for sealant placement. Much of the data, particularly personnel salaries, the quantities of materials used in the intervention, instruments, and equipment were obtained from study expenditure records at the School and Hospital of Stomatology in Wuhan. In the case of items purchased or donated that are not available in China, the replacement cost was obtained in euros or dollars, converted to yuan, and adjusted to 2010 values. The costs of traveling to and from the schools were reported by the operators (14). Capital expenditures for equipment were annualized at a rate of 3% (18).

The intervention consisted of 92 morning and afternoon sessions over a period of 10 weeks (14). Two methods were used to estimate the costs of intervention delivery. Activity sampling (19) was used to measure personnel time during implementation of the sealant application intervention through self-reporting by the dental assistant who helped the operating dentist. In 15-minute intervals, using a countdown timer, the operators captured session activities. These fell into the following categories: clinical activities (e.g. examination, diagnosis, and treatment); complementary activities (e.g. treatment preparation, awaiting patients); and other activities that captured downtime resulting from equipment failure or patient or operator absence (14). In addition, each sealant placement was measured during the intervention by recording the time at the start and end of each procedure (14).

To adjust for variability in the number of sealants per intervention group in the community trial, the cost-effectiveness analysis projected the total cost of performing 1,000 sealants, the number of new, cavitated dentine carious lesions per 1,000 sealants, and the cost of restorations per 1,000 sealants for each of the four interventions. This conversion aided in the comparison of the total costs and effectiveness of the four groups and is more applicable to a government school program, in which large numbers of sealants would be placed. Producing more sealants implies increasing supplies of restoration materials, etc. This was carried out at the same rate as for the sample. The cost of equipment for the sample for 2 months was estimated at about 16.6% of the annual equipment cost. For the projection, this amount was increased proportionately to 35.8% of the annual cost. The impact of economies of scale would not begin to show until higher numbers of sealants were produced. Another projection of producing about 6,000 sealants over a year was created to evaluate the impact, on costs, of economies of scale.

The original cost per sealant obtained for the 2-year analysis was the starting point for the evaluation of costs after 4-years. The costs for restoring new cavitated lesions seen in the 3- and 4-year evaluations were treated in the same way as they were treated at 2 years (14). A cavitated lesion triggered the cost of a restoration. The restoration costs were added to the cost of performing the sealants to produce a net cost. All outcomes and costs, including adverse-events costs, were discounted for each year at 3% (18) and were adjusted to 2010 values, as were the costs of treatment. Outcomes and costs are examined using an incre-

mental cost-effectiveness analysis framework, where the interventions are ranked according to effectiveness, and the differences in costs and effectiveness are calculated to produce an incremental cost-effectiveness ratio (ICER) (20). The ICER summarizes the additional cost of preventing one dentine carious lesion when switching to the next most-effective intervention. In this study, the ICER represents the difference in the total costs of two sealant interventions and the adverse events costs divided by the difference in the number of dentine carious lesions associated with each intervention (20).

Sensitivity analyses are used to estimate the influence and range of different variables on the results of cost estimates and cost-effectiveness analyses (20). The sensitivity analyses were repeated on the 4-year results to evaluate changes in the probability of the development of dentine carious lesions, as well as increases in input costs (such as personnel, instruments and supplies, and equipment), on sealant costs and cost-effectiveness.

The computed indicator of cost-effectiveness must be evaluated against subjective thresholds that determine the desirability of projects within the constraints and goals for implementing interventions. Such a threshold would be considered a government's willingness to pay. These thresholds will depend on context and general policy guidelines across various settings. In developing countries, approaches that reference the decision maker's valuation of a unit of health gain have been used in the normative assessment of cost-effective measures (21).

One such approach follows World Bank recommendations for a minimum health package in 1993 in which interventions valued at US$150 per DALY are considered acceptable for low-income countries (21). The DALY was chosen in this analysis because it has been used by nations, international organizations (such as the World Bank and the WHO), as well as academics, to measure health status globally.

In the 2-year report for this study (14), the burden of disease estimate for dental caries for East Asia (2,3), of 222 DALYs per 100,000 persons, was used to estimate the DALY impact for the study. The global DALY estimate for untreated dental caries in the permanent teeth in 2010 was 73 per 100,000 persons (2), or 0.73 DALYs per 1,000 persons. Applied to the 407 children in the study with a total of 1,859 sealants, at an average of close to 4.57 sealants per child, the health loss for 1,000 children would be about 3.2 DALYs per 1,000 children, or 0.3%

of a DALY per child (14). This information was used in the comparison of the new ICERs produced for this 4-year study.

The study results are reported in US dollars. Most of the cost data were collected in yuan. All costs were adjusted for inflation and converted to US dollars in 2010. Data for currency exchange rates and the GDP inflation deflator were obtained from the World Bank World Development Indicator database (22).

Statistical analysis

Data collected after 2 and 4 years were analyzed using survival analysis techniques, including the Kaplan-Meier method, supplemented by the jackknife method used to calculate standard errors (SE) of the survival percentages, thereby to account for the dependence of data on different sealants in one child. After 4 years the investigators discovered that some tooth surfaces had been sealed despite containing small cavitated dentine carious lesions, violating the study's inclusion criteria. In reviewing these data for this cost-effectiveness analysis, 101 tooth surfaces were eliminated from the sample, and thus 1,758 of the 1,859 sealants, originally performed, remained for analysis. The cost calculations reported here are based on the original 1,859 sealants placed because excluding the 101 tooth surfaces would artificially inflate the cost per sealant placed.

D_2MFS (enamel carious lesion, missing, filled teeth in permanent dentition) and D_3MFT (dentine carious lesion, missed, filled teeth in permanent dentition) counts describe individuals' caries experience for enamel and dentine caries, respectively. The caries-experience effect between the four sealant groups at baseline and after 4 years was tested using ANOVA. Effectiveness in preventing dentine carious lesions at 4 years was assessed using the *t*-test and jackknife SE with an alpha-value for a significant difference of $P = 0.05$ (14). Data imputation was performed to evaluate loss to follow up.

Calculation of the cost of performing one sealant was performed by summing the costs of materials, equipment, transportation, and personnel time by dividing them by the number of sealants performed for each group (14). Mean values for personnel time per activity performed in each session were also estimated using SAS 9.3 (SAS, Cary, NC, USA) for the

activity sampling data, as were mean values for sealant placement times recorded directly in each session (14).

Results

Sample

Table 3.1 shows the intervention baseline characteristics and results after 2 and 4 years. The number of children remaining in the study sample was approximately 90% of those who originally participated: 92% in the glass-carbomer group; 91% in the composite resin group; 90% in the LED thermocured HVGIC group; and 87% in the HVGIC group. Sample attrition was close to 12.3%. This translated into a loss to follow up of approximately 15% of all sealants placed. There were also differences between the costs of performing one sealant for the sample and the projection of 1,000 sealants performed (Table 3.2). The costs of HVGIC and glass-carbomer were lower, at US$4.04 and US$6.89, respectively. For LED thermocured HVGIC the cost of producing one sealant stayed the same, at US$4.65, while the cost of producing one composite resin sealant increased to US$3.47. The costs for all four groups dropped dramatically in the results for the projection of 6,000 sealants per group, ranging from US$1.70 for composite resin to US$3.25 for glass-carbomer.

Table 3.1: Intervention baseline characteristics and results (mean scores ± SD) after 2 years and 4 years, according to treatment group

	Study Group			
Study time point/variable	**HVGIC**	**LED thermo-cured HVGIC**	**Glass-carbomer**	**Composite resin**
Baseline				
Children	97	103	98	107
Sealed pits and fissures	416	474	413	455
Occlusal sealants	290	330	308	338
Free-smooth sealants	126	144	105	117
$d_3$mft	4.8 ± 2.6	4.9 ± 2.6	4.7 ± 2.6	5.0 ± 2.4
D_3MFT	0.2 ± 0.6	0.2 ± 0.5	0.1 ± 0.4	0.1 ± 0.5
2 years				
Children	89	98	91	102
Sealed pits and fissures	387	449	377	427
Dentine carious lesion	7	5	10	5
Increment				
$d_3$mft	4.1 ± 2.5	4.1 ± 2.4	4.3 ± 2.7	4.0 ± 2.5
D_3MFT	0.3 ± 0.7	0.3 ± 0.6	0.3 ± 0.7	0.2 ± 0.6
Effectiveness	98.3%	99%	97.4%	98.9%
4 years				
Children	84	93	90	98
Sealed pits and fissures	345	405	341	396
Dentine carious lesion	9	7	19	14
Increment				
D_3MFT	0.6 ± 1.4	0.3 ± 0.8	0.3 ± 1.1	0.3 ± 0.8
Effectiveness	97.3%	98%	94.5%	96.4%

$d_3$mft, dentine carious lesions in the primary teeth; D_3MFT, dentine carious lesions in the permanent teeth; HVGIC, high-viscosity glass-ionomer cement; LED, light-emitting diode. Values are given as *n*, mean ± SD or, where indicated, as %.

Incremental cost-effectiveness

When the study data were ranked according to incremental cost-effectiveness for comparison after 4 years, the glass-carbomer group (Table 3.3), with the worst outcome of 17 cavitated dentine carious lesions, was the most expensive at a total cost of US$3,738.

It was followed by composite resin, the least costly material, at a total cost of US$1,675 with 13 associated cavitated dentine carious lesions. Next in the ranking were the costs for the two high-viscosity glass-ionomer groups, US$2,095 with nine cavitated dentine carious lesions for the HVGIC group and US$2,363 with seven cavitated dentine carious lesions for the LED thermocured HVGIC group. Thus, when comparisons were made between pairs of groups, for the sample data, HVGIC was more effective than the composite resin, while LED thermocured HVGIC was more effective than HVGIC and composite resin. The ICER for the comparison of HVGIC and composite resin was US$105 for the sample data. When the LED thermocured HVGIC and HVGIC groups were compared with each other, the resulting ratio was US$134. The ICER produced by direct comparison between the LED thermocured HGVIC and the composite resin groups was US$115.

Table 3.2: Net cost (US$2,010) per sealant, intervention sample, and projections, according to group, at baseline, 2 years, and 4 years

	Study group			
Variable	**HVGIC**	**LED thermocured HVGIC**	**Glass-carbomer**	**Composite resin**
A. Cost of performing one sealant at baseline				
Sample	4.57	4.65	7.84	3.05
Projection (1,000 sealants/group)	4.04	4.65	6.89	3.47
Projection (6,000 sealants/group)	1.81	2.06	3.25	1.70
B. Net cost per sealant after 2 years (includes adverse effects cost, i.e. restoration of cavitated carious dentine lesions)				
Sample	4.94	4.89	8.39	3.30
Projection (1,000 sealants/group)	4.47	4.83	7.50	3.73
C. Net cost per sealant after 4 years (includes adverse effects cost, etc.)				
Sample	5.03	4.98	9.05	3.68
Projection (1,000 sealants/group)	4.54	4.91	7.88	4.12
Projection (6,000 sealants/group)	4.35	4.78	7.51	3.81

HVGIC, high-viscosity glass-ionomer cement; LED, light-emitting diode. A. Cost for performing one sealant (US$2,010) estimated from the study sample cost data and the projections of 1,000 and 6,000 sealants performed per group. B and C. Net cost per sealant at 2 and 4 years, respectively, for the intervention sample and the projections, including placement costs and restoration costs for surfaces that developed carious lesions, according to group.

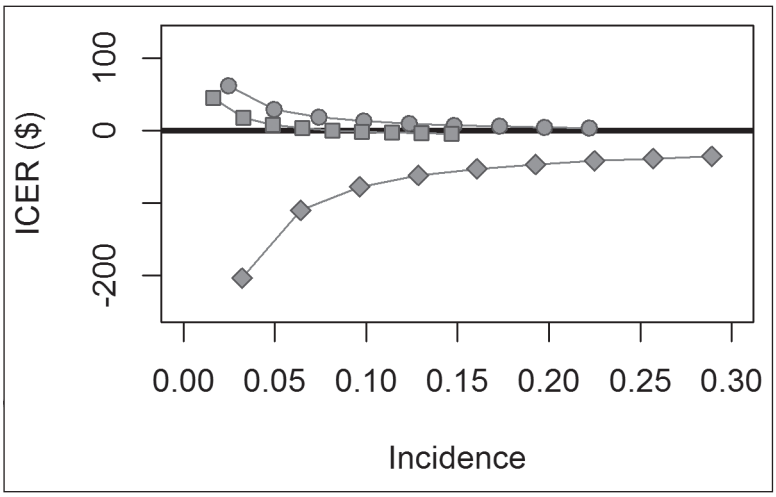
Table 3.3 also shows the ICER values for the projections of 1,000 and 6,000 sealants per group, which demonstrate a similar trend for overall incremental cost-effectiveness except that the ICER values were lower. The ICER for the comparison of HVGIC with composite resin was US$59 for each additional cavitated dentine carious lesion that occurred and was treated, per 1,000 sealants placed in each group (Table 3.3). The comparison between the LED thermocured HVGIC and HVGIC groups resulted in an ICER of US$40 per additional cavitated dentine carious lesion per 1,000 sealants placed. When a direct incremental comparison was made between LED thermocured HVGIC and composite resin, the ICER was US$52 per additional cavitated dentine carious lesion between both groups. With the projection of 6,000 sealants per group, also comparing LED thermocured HVGIC with composite resin resulted in an ICER of US$65 per additional cavitated lesion treated per 1,000 sealants placed.

Table 3.3: Incremental cost-effectiveness ratios (US$2,010) for the sample, and projections of 1,000 and 6,000 sealants per group after 4 years*

Intervention	Cost† ($)	Effectiveness, new cavitated dentine carious lesions (n)	Incremental cost ($)	Lesions prevented (n)	Cost per lesion prevented ($)
Sample					
Glass-carbomer	3,738	17			DOMINATED
Composite resin	1,675	13			DOMINATED
HGVIC	2,095	9	419	8	105
LED thermocured HVGIC	2,363	7	268	8	134
Direct comparison between composite resin and LED thermocured HVGIC groups					
Composite resin	1,675	13			DOMINATED
LED thermocured HVGIC	2,363	7	688	6	115
Projection 1,000 sealants per group					
Glass-carbomer	7,888	49			DOMINATED
Composite resin	4,138	30			DOMINATED
HGVIC	4,552	24	415	8	62
LED thermocured HVGIC	4,916	15	472	8	45
Direct comparison between composite resin and LED thermocured HVGIC groups (projection of 1,000 sealants per group)					
Composite resin	4,138	30			DOMINATED
LED thermocured HVGIC	4,916	15	472	8	52
Projection 6,000 sealants per group					
Glass-carbomer	45,050	292			DOMINATED
Composite resin	22,884	182			DOMINATED
HGVIC	26,095	142	2,562	49	52
LED thermocured HVGIC	28,657	93	5,773	89	65
Direct comparison between composite resin and LED thermocured HVGIC groups (projection of 6,000 sealants per group)					
Composite resin	22,884	182			DOMINATED
LED thermocured HVGIC	28,657	93	5,773	89	65

HVGIC, high-viscosity glass-ionomer cement; LED, light-emitting diode.
*Costs and outcomes have been discounted by 3%.
†Costs include those of applying the sealant and those to restore lesions that occur in the 4-year period following sealant application. DOMINATED indicates there are other more effective and ultimately less expensive options.

Figure 3.1 illustrates the results of the sensitivity analysis performed on the effect of an increase in the probability of caries (cavitated dentine carious lesion) incidence on the ICER for the composite resin, HVGIC and LED thermocured HVGIC groups. The ICER decreased as the probability of dentine carious lesions occurring increased, for both HVGIC groups, in particular, the LED thermocured HVGIC group, which showed a turn-around from a cost to a saving. At the same time, the saving indicated by the composite resin ICER decreased as the ICER approached zero.



Other sensitivity analyses conducted on personnel, instruments and supplies affected the cost of sealant placement in different ways. Simultaneous one-way analysis of increases in the cost of instruments and supplies affected the high-viscosity glass-ionomer groups more (12%) than the composite resin group (9%). Simple one-way increases in personnel affected the price of a composite resin sealant more (14%), while the impact on the high-viscosity glass-ionomer groups was smaller (11–12%). For equipment, the price for the composite resin group increased by 6% and that for LED thermo-cured HVGIC increased slightly, by 1%.

The DALY calculations based on the sample (14) estimated a loss of 3.2 dentine carious lesions over 1,000 restorations performed. Application of this estimated loss to the results of the 4-year ICERs for preventing one additional cavitated dentine carious lesion using LED thermocured HVGIC compared with composite resin produces a cost below the US$226 per DALY threshold in both the sample and the projected data.

Discussion

This 4-year report of the cost-effectiveness of the materials evaluated in the Wuhan community trial builds on the methods established in the 2-year report of this study (14), and the results at 4 years are congruent with the trends in the outcomes seen in the sensitivity analyses in the earlier report. Both reports sought to follow established methods in carrying out cost-effectiveness analyses, in terms of reporting the methods used to obtain and analyze costs and outcome data, the adjustment of costs over time, discounting both costs and outcomes, and sensitivity analyses. Reviews of reports of economic evaluation research in dentistry over time by Källestål *et al.* (23), Mariño *et al.* (24) and, most recently, Tonmukayakul *et al.* (25) have pointed to the need to improve the methodological quality of these studies.

After 4 years, all sealant materials demonstrated a high level of effectiveness in preventing cavitated dentine caries lesions, with survival of the number of sealed pits and fissures being >94%. In this study, the glass-carbomer had the least favorable results and was the most expensive material, leading to the rejection of the first of the two hypotheses of the study. The second hypothesis was also rejected as there was no significant difference observed between the LED thermocured high-viscosity glass-ionomer and the high-viscosity glass-ionomer groups.

The incremental cost-effectiveness results show the incremental differences between the materials evaluated in the study in terms of their preventive capabilities. LED thermocured HVGIC had the lowest number of newly developed dentine carious lesions, and the ICER illustrates the difference in costs between LED thermo-cured HVGIC and composite resin per lesion to prevent each of the 50% fewer additional lesions prevented by LED thermocured HVGIC. While ICERs address incremental cost-effectiveness, policy makers will want to understand how this translates into program implementation costs. The additional cost per LED thermocured HVGIC restoration over composite resin is US$1.70 for producing 1,000 sealants and US $0.96 for producing 6,000 sealants.

In the previous 2-year report for this study (14), the cost of US$1,106 per caries lesion prevented per 1,000 sealants placed was deemed too expensive in terms of what many countries would be willing to pay, depending on their economic conditions. At this juncture,

however, the threshold of US$226 per DALY applied to the resulting ICERs shows that a school-based sealant project, such as this one, which costs less than US$226 per DALY, would fall within a range of what would be considered 'cost-effective' and that government policy makers would consider feasible.

The sensitivity analyses performed on variations in the probability of cavitated lesions occurring in the study at 2 and 4 years show that as the number of cavitated lesions increases, the costs for implementing LED thermocured HVGIC decrease. This supports the conclusion that LED thermocured HVGIC is more cost-effective than HVGIC without heat or composite resin, even though it is not the least cost-saving method.

The accuracy of the estimates, supported by the fact that activity sampling was conducted on 80% of the sample, is a strength of the study (14). The exclusions made upon the discovery, after 4 years, that 101 tooth surfaces were sealed in violation of the study's inclusion criteria, and also the numbers of children and sealants lost to follow up, may have somewhat inflated the cost per sealant and could be considered as limitations.

Cost-effectiveness is one of several factors that should be evaluated in the process of deciding the practicality and desirability of a sealant material. Other relevant factors include technical and administrative feasibility, the ambient conditions required for applying the material, the probable compliance rate with the treatment protocol, and the portability of the approach in terms of the ability to reach large numbers of the population (14). The relatively low loss of children participating in the study over 4-years points to the viability of a strategy that targets children in schools. While all sealant materials displayed a high level of viability, LED thermocured HVGIC has the advantage that it can be delivered as a mobile service in environments beyond the dental clinic, even beyond mobile dental clinics, and thus is capable of more comprehensively reaching all members of the population in countries struggling with limited access to oral health care. Its ease of application in terms of minimal technical and infrastructure resource needs, combined with its cost-effectiveness, make LED thermocured HVGIC (the most cost-effective method) a viable option with economic appeal to capital-deprived countries and general settings of resource scarcity.

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Chapter 4

Treating high-caries risk occlusal surfaces in first permanent molars through sealants and supervised toothbrushing: A 3-year cost-effective analysis

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Abstract

We conducted a 3-year cost-effectiveness analysis on the cavitated dentine carious lesion preventive capabilities of composite resin (CR) (reference group) and atraumatic restorative treatment (ART) high-viscosity glass-ionomer cement (HVGIC) sealants compared to supervised toothbrushing (STB) in high-risk first permanent molars. School children aged 6 to 7 years in 6 schools (2 per group) received CR and ART/HVGIC sealants or STB daily for 180 days each school year. Data were collected prospectively and cost estimates were made for sample data and a projection of 1,000 sealants/STB high-risk permanent molars. Although STB had the best outcome, its high implementation cost (95% of cost for supervisors visiting schools 180 days/school year) affected the results. ART/HVGIC was cost-effective compared to CR for the sample data (savings of USD 37 per cavitated dentine carious lesion prevented), while CR was cost-effective compared to ART/HVGIC for the projection (savings of USD 17 per cavitated dentine carious lesion prevented), and both were cost-saving compared to STB. Two STB scenarios were tested in sensitivity analyses with variations in caries incidence and number of supervision days; results showed STB had lower costs and higher savings per cavitated dentine carious lesion prevented than CR and ART/HVGIC. A major assumption is that both scenarios have the same high effectiveness rate experienced by STB under study conditions; however, they point to the value of further research on the benefits of adopting STB as a long-term venture in a general population of schoolchildren.

Introduction

Sealing high-caries risk pits and fissures in permanent molars is a well-established method for preventing carious lesion development, both in the clinic (1) and in outreach situations (2–4). Compared to similar pits and fissures that have not been sealed, effectiveness is high in dentine carious lesion prevention (1). Even compared to similar pits and fissures treated according to a fluoride varnish regime, the effectiveness of sealants in the prevention of dentine carious lesions is higher (5–6).

Either a resin-based or a glass-ionomer-based material is used for placing a sealant. It is generally accepted that resin-based sealants are retained longer than glass-ionomer-based sealants (7). However, the dentine carious lesion preventive effect between these 2 types of sealants is not significantly different (1,6,8,9).

One aspect of the atraumatic restorative treatment (ART) approach consists of sealing high-caries risk pits and fissures using a high-viscosity glass-ionomer cement (HVGIC). Four studies have shown the effectiveness of ART sealants in preventing dentine carious lesions to be higher than or equivalent to that of resin-based sealants: ART sealants were more effective after 5 years (3), and identical after 4 years (10), 3 years (11), and 2 years (4). Because ART sealants can also be applied outside the clinical environment, this preventive method is suitable for use in school oral healthcare programs.

The minimal intervention dentistry philosophy considers dental caries to be primarily a behavioral disease (12). Proper biofilm and diet control will go a long way in managing dental caries for many (13,14). Being mindful of that, practicing regular biofilm removal from vulnerable occlusal tooth surfaces in just-erupted teeth under supervision might prevent carious lesion development to a large extent (15). However, unlike sealant prevention effectiveness, the dentine carious lesion prevention effectiveness of cleaning high-caries risk pits and fissures under supervision, or supervised toothbrushing STB), has not been studied much. A recently published study showed no statistically significant difference in the effectiveness of resin-based and ART/HVGIC sealants in comparison to daily STB in high-caries risk occlusal surfaces of first permanent molars after 3 years (11).

Whilst a sizable number of studies have been carried out regarding the dentine carious

lesion prevention effectiveness of sealants of different materials, relatively few studies have been performed that provide information on the costs and cost-effectiveness associated with sealants and other preventive measures (16–18). Given the advancement in dental caries prevention interventions and the paucity of research on the costs and cost-effectiveness associated with sealants and other preventive measures, a cost-effectiveness analysis was conducted as part of a sealant community trial that was performed in a resource-strapped area of Brasília, Brazil (11).

The trial sought to evaluate approaches to preventing the development of cavitated dentine carious lesions on the first permanent molars; these were composite resin (CR) sealants, ART-HVGIC sealants, and STB. The study's objectives were (i) to calculate the cost per sealant in 2 of the study groups and the cost per permanent occlusal molar in the STB group after 3 years, and (ii) to determine the incremental cost-effectiveness of the sealants and that of STB of first permanent molars given their rates of survival after 3 years.

Materials and Methods

The study was accepted by the Research Ethics Committee of the University of Brasília Medical School (reference No. 081/2008) and was registered at the Netherlands National Trial Register (reference No. 1699). Parents and/or caretakers were informed in writing about the investigation and treatments. Details of the study were published previously (11) and a summary is provided below.

Sampling procedure

This cluster-randomized controlled clinical trial was carried out in all 6 public primary schools of Paranoá, a low-income suburban area of Brasília whose water system was artificially fluoridated. Prior to the trial, which used a parallel-group design, an epidemiological survey of 6- and 7-year olds attending these schools was carried out (19). The study inclusion criteria were as follows: (1) good general health; (2) at least 2 cavitated dentine carious lesions in vital pain-free primary molars, assessed according to the second digit of the ICDAS II (International Caries Detection and Assessment System); (3) erupted first permanent molars, with the

occlusal surface fully visible and accessible; (4) high-caries risk occlusal surfaces in first permanent molars, determined by ICDAS II codes 2 and 3 or by a combination of ICDAS II code 1 and medium or deep fissures (assessed according to Symons et al. (20); and (5) a consent form signed by the child's parent or caretaker.

The study compared 3 groups for treatment of high-caries risk occlusal surfaces: STB and 2 types of sealants (CR sealants, which are applied with conventional methods and rotary equipment, and ART/HVGIC sealants). CR sealants were considered the reference group.

The sampling unit was the school (2 schools per group). As 2 of the 6 schools were equipped with a dental unit, these schools were allocated to the CR group. The remaining 4 schools were randomly allocated to the ART/HVGIC and STB groups. There were no differences amongst the 4 groups with respect to dmfs (21) and it should be noted that the units in the CR group schools had not been used in 5 or 6 years. At the start of the study and during the evaluation periods, all children were individually instructed by the dentist on how to brush their teeth.

Study implementation

Sealants were placed by 3 trained and calibrated pedodontists who were aided by trained dental assistants, between May and July 2009, on the school premises. Toothbrushing was supervised from May 2009 to December 2012. All children received an oral hygiene kit containing a toothbrush, a 1,000-ppm fluoridated toothpaste, plaque-disclosing paste, and dental floss. They were instructed on how to use these devices and were encouraged to brush their teeth twice daily. Before the sealant treatment started, pits and fissures were cleaned with toothbrush and toothpaste.

CR Sealant Group. The children were positioned in a dental chair containing an operation lamp. Isolation was obtained using cotton wool rolls and a suction device. The occlusal surface was cleaned with a rotating brush, acid etched for 30 s with 37% phosphoric acid (Acigel, SSWhite, Rio de Janeiro, Brazil), rinsed, and dried with a 3-way syringe. The sealant material, Fluoroshield (Dentsply, Petrópolis, Brazil), was placed in a dappen glass, transported to pits and fissures with a ball-ended probe (Duflex, Rio de Janeiro, Brazil), and light-cured for

40 s (Ultralux; DabiAtlante, Ribeirão Preto, Brazil). Occlusion was checked with carbon paper and adjusted when necessary with rotary instruments.

ART/HVGIC Group. The children lay on a portable bed. The treatment used artificial light from a portable headlamp. Isolation was obtained with cotton wool rolls. Plaque was further removed from the occlusal surface with a dental probe and cotton wool pellets. The occlusal surface was conditioned with polyacrylic acid for 10–15 s and washed and dried with wet and dry cotton wool pellets, respectively. Ketac Molar Easymix (3MESPE; Seefeld, Germany) was hand-mixed according to the manufacturer's instructions, applied on the occlusal surface with an ART applier instrument (Henry Schein, Chicago, IL, USA), and pressed into pits and fissures by a petroleum jelly coated finger for 15 s (22). Excess material was removed with the ART-carving instrument after bite registration with carbon paper. The sealant was coated with petroleum jelly, and the children were told not to eat for 1 h.

STB Group. The children were instructed to clean their teeth at least twice a day, and on every school day a dental assistant, trained in identifying plaque, supervised the toothbrushing sessions. Brushing instructions were repeated if needed. Special attention was given to brushing medium and large tooth cavities in primary teeth in order to keep them plaque free. A conventional toothbrush and fluoridated toothpaste were used. The children were encouraged to maintain the same hygiene pattern at home and during school vacations.

Evaluation

Using ICDAS II, 2 independent evaluators (dentists) assessed the study teeth for the presence of carious lesions on the school premises after 6 months and 1, 2, and 3 years. They were trained and calibrated before each evaluation session by an experienced dental epidemiologist (J.E.F.). The evaluation was aided by battery-illuminated dental mirrors (Kudos, Hong Kong, China), a CPITN probe (Golgran, São Caetano-do-Sul, Brazil), and compressed air. The kappa coefficient value was 0.76 for the inter-evaluator consistency test in assessing carious lesions over the 4 evaluation times. The percentage of agreement of scores was 86.7%.

Cost-effectiveness study design and data collection

This study evaluated the cost-effectiveness of 3 distinct approaches to caries prevention in the occlusal surfaces of high-risk permanent first molars in school children in Brazil. The intent of the study was to inform government decisions on the economic viability and effectiveness of population-based solutions for oral health. Given its objective to inform oral health policy-makers, the study perspective adopted was one of a government program. Because the study evaluated 3 distinct approaches, incremental cost-effectiveness was chosen as the method of evaluation (23,24).

To assess whether the parameters of the findings in the study data hold in a larger population, the study results were also applied to a projection of 1,000 sealants/high-risk molars per group. Inputs such as personnel time, instruments and supplies, and transportation were increased proportionally, at the same rate as they occurred in the study sample. In addition, the sizes of the groups were uneven, so creating the projection standardized all the groups. Annualized equipment costs were applied according to the proportion of time it took to create the number of sealants in the sample (4.5% per year) and the projection (25% per year for 1,000 sealants).

The incremental cost-effectiveness ratio (ICER) represents the cost associated with preventing an additional adverse outcome (in this study, cavitated dentine carious lesion) for each intervention strategy. It provides a measure of the cost per unit of effectiveness for each of the different alternative intervention strategies. The ICER calculation takes into consideration the total implementation costs of each intervention strategy and the cost of the total number of adverse events associated with each strategy. In this methodology, the intervention strategy with the worst effectiveness outcome is used as the base against which the other strategies are compared (23,24). For this study, CR is considered the reference group; however, the comparisons were made according to the groups' effectiveness.

In the ICER calculation for the study sample, the difference in the costs between the 2 sealant methods was first obtained by subtracting the total cost of CR (reference group) from the total cost of ART/HVGIC. Next, the number of cavitated dentine carious lesions for ART/HVGIC were subtracted from those for CR. Finally, ART/HVGIC and CR were compared in a ratio where the difference in the costs of the interventions was divided by the difference in the effec-

tiveness of the interventions. This process was repeated for the STB-ART/HVGIC comparison. In the projection of 1,000 sealants or molars under supervision per group, ART/ HVGIC had the lowest effectiveness in the projection so it became the base, followed by CR and STB.

The principal outcomes evaluated consisted of the cost-effectiveness of the 3 approaches to preventing dentine carious lesions on the first permanent molars and the cost and net cost per dentine carious lesion prevented. Net costs included intervention plus adverse events costs, in this case the development of cavitated dentine carious lesions on the first permanent molars and the cost of restoring these lesions. First permanent molars that developed dentine carious lesions were restored in keeping with each protocol; the restoration costs were added to the costs of the corresponding program. The study horizon was 3 years.

Study cost data, including personnel, transportation, equipment, and instruments and supplies purchases and donations, were recorded prospectively, making it a financial analysis. Most of the data collected for these inputs were obtained by the principal investigators from the University of Brasília using a Microsoft Excel instrument designed specifically for the Brasília study. The data included the salaries of the pedodontists and their assistants, their transportation costs, and costs for equipment and instruments and supplies. In the case of capital items used in the study, but not ac quired for it, such as the dental chairs in 2 of the schools, their replacement cost was used. Costs of instruments and supplies were recorded by group. Transportation and equipment costs were apportioned by group according to the number of interventions performed in each group. This was done with personnel costs as well, but time was also factored into the equation.

The time the pedodontists and their assistants spent in treating patients is an important element of costing. These data were collected in 2 ways. Sealant performance time was recorded by the assistant on the study data form. Dental assistants recorded the time to perform a sealant beginning with the moment the pedodontists lifted their instruments until the moment they put them down once finished. The second method, the activity sampling method (25), was used to evaluate the reliability of the data collected in the study as well as to collect data on the entirety of the implementation sessions, in order to include treatment and other ancillary activities.

Approximately 30 four-hour intervention sessions were sampled in 15-minute intervals using a countdown timer. To avoid bias of sampling the same intervals each day, the timer was set

at a different time after the session began at 8:00 a.m. The number of minutes after 8:00 a.m. was determined by the last digit in the ID number of the first participant. Each time the timer went off, the assistant would record what the pedodontist was doing in the space for that interval on the data collection sheet for that session. Activities were categorized as clinical (e.g., performing an examination or a sealant), complementary (e.g., instrument preparation), or non-clinical (e.g., equipment failure, coffee break, patient absent).

Study outcomes, including effectiveness data, costs incurred in implementation, and adverse events costs, were discounted at a rate of 3% (26). The value of capital equipment was annualized at a rate of 3%. Costs were recorded in reais (BRL), the Brazilian currency. For items purchased or donated from other countries their cost was converted to reais. The World Bank GDP inflation deflator was used to adjust costs incurred in 2009 when the study began and others incurred as it progressed to 2012 values (27). These were later converted to 2012 USD values for this report; this conversion did not account for purchasing power parity.

Analysis

Sealant performance time data were entered into the study's main database and analyzed using SAS® 9.3 (SAS Institute, Cary, NC, USA) to obtain means and standard errors. The cost per sealant was estimated by calculating the proportion of personnel time devoted to sealants and adding to it the costs of instruments and supplies for sealants, as well as a proportion of transportation and, when applicable, equipment costs. The activity sampling data for each sampling session were entered into a Microsoft ACCESS database and the entries were verified by 2 different persons. The data were transposed to SAS and analyzed to obtain the mean time to perform clinical activities, particularly sealants, as well as complementary and other non-clinical activities. Activities per session were counted in SAS and used to estimate the proportion of time spent on each activity. Further calculations converted this proportion into the number of minutes per activity. The data were programmed into the Microsoft Excel instrument which was set up to calculate implementation costs as well as net costs, which included the cost of restorations for the surfaces that developed cavitated dentine lesions, to calculate the cost per sealant placed.

Sensitivity analyses conducted on the results sought to evaluate the impact of variations

in the number of STB visits and the incidence of cavitated dentine lesions on the resulting ICER. In the expectation that the resulting cost of the STB (dental assistants visiting schools 180 days/year) is not sustainable for a government program, 2 alternative scenarios were created to evaluate the impact on costs of fewer STB visits. Both scenarios propose that the dental assistants conduct visits over 1 year when children are in first grade to ensure that toothbrushing becomes a habit. Scenario 1 envisions 36 weekly visits per school year and the development of about 33% more cavitated dentine carious lesions compared to 9 monthly visits per year and about 52% more cavitated dentine carious lesions for scenario 2. Both scenarios rely on the assumption that they will have similar effectiveness over 3 years. This is a strong assumption which should be investigated more thoroughly in the future.

Results

Effectiveness

Table 4.1 displays the baseline characteristics and status at 3 years of the study sample: 169 composite resin and 69 ART/HVGIC sealants were applied and 71 first permanent molars were targeted in the STB group. After three years, the effectiveness of the three groups in preventing dentine carious lesions in the molars was greater than 90% (91.4% for composite resin, 90.2% for ART/HVGIC, and 95.6% for STB) (11).

Table 4.1: Intervention baseline characteristics for high-risk sealed molars and status at 3 years

	Treatment Groups*		
	Composite Resin (CR)	**ART/HVGIC**	**STB**
Baseline			
Schools (n)	2	2	2
Children (n)	70	37	38
Sealants (n)	169	69	71
D_3MFT (SE)	0.27 (0.56)	0.27(0.51)	0.23(0.42)
$d_3$mft	6.11(3.12)	5.78(3.94)	5.18(2.51)
3 years			
Children (n)	47	27	28
Sealants (n)	120	51	50
Dentine carious lesion increment (n) [cumulative]	12	6	3
Effectiveness [cumulative] SE	**91.4% (2.9)**	**90.2%(5.0)**	**95.6%(2.5)**

*CR, composite resin; STB, supervised toothbrushing; ART/HVGIC, a traumatic restorative treatment/high-viscosity glass-ionomer cement; SE, standard error.

Table 4.2: Breakdown of inputs for CR and ART/HVGIC sealants for the study sample

	Treatment Groups		
Input	**Composite Resin (CR)**	**ART/HVGIC**	**STB**
Personnel	54%	42%	95%
Instruments and supplies	38%	56%	5%
Equipment	4%	0%	
Transportation	4%	2%	

Data are presented as a percentage of intervention costs. CR, composite resin; ART/HVGIC, atraumatic restorative treatment/high-viscosity glass-ionomer cement; STB, supervised toothbrushing.

Inputs

A breakdown of the percentages of the inputs (resources) that went into each of the sealant approaches and the STB approach are shown in Table 42. In all 3 approaches the highest percentage of inputs went to personnel: 54% for CR, 42% for ART/HVGIC, and 95% for STB. For the ART/HVGIC and CR groups the next highest percentage was for materials and supplies, at 8 and 56%, respectively.

Costs

Table 4.3 displays the findings concerning the 2 different types of sealants in terms of application time per sealant, the cost and net cost of performing sealants, and the cost of 180 days of STB per year each year for 3 years. The treatment time for the application of the ART/HVGIC sealants was about 50% more than that for CR. The cost of performing the ART/HVGIC sealant was almost twice as high as for the CR application in both the sample and the activity sampling data. Nonetheless, this difference decreased as the number of sealant applications reached 1,000. The reduction came about through a decrease in cost for ART/HVGIC from USD 7.22 in the sample to USD 4.86 in the projection as well as an increase in the cost associated with the application of CR, from USD 3.74 to USD 4.81. For the STB initiative, the costs of supervising the molars in the STB group 180 days per year for 3 years for the study sample were USD 18.56, at least 2.5 times higher than the sealant application method. This trend was repeated in the findings on the net cost per sealant.

Table 4.3: Time to perform sealants and sealant/caries-free molar costs (US 2012) according to treatment group* (baseline performance and net costs) for the sample (recorded times) and activity sampling data; and a projection of 1,000 sealants/ STB brushing of caries-free molars per group, respectively.

	Treatment Group		
	CR sealants	**ART-HVGIC sealants**	**STB 180d/yr**
Mean treatment time per sealant (min) SD			
Sample (recorded) (SE)	4.50 (0.92)	6.00 (1.4)	
Activity sampling (SE)	6.77 (1.26)	9.58 (1.09)	
Cost of performing sealant/STB per molar			
Sample	3.74	7.22	18.56
Activity Sampling	4.75	6.96	18.56
Projection of 1,000 sealants	4.81	4.86	8.82
Net cost per sealant/STB per molar (including adverse event costs)			
Sample	4.37	8.02	18.56
Activity Sampling	5.39	7.75	18.56
Projection of 1,000 sealants	5.32	5.51	9.14

*CR, composite resin; STB, supervised toothbrushing; ART-GIC, atraumatic restorative treatment/high-viscosity glass-ionomer cement.

Incremental cost-effectiveness

Table 4.4 shows the data and the results for incremental cost-effectiveness per cavitated dentine carious lesion. The comparison of ART/HVGIC and CR in the sample data resulted in a savings of USD 37 per new cavitated dentine carious lesion prevented in favour of ART/HVGIC. When STB (where 180 STB visits took place per year) was compared to ART/HGVIC, the cost per cavitated dentine carious lesion prevented was USD 264. When CR was compared to STB in the projection of 1,000 sealants per group it had a better outcome than STB with cost savings of USD 17, compared to a cost of USD 140 for STB per cavitated dentine carious lesion prevented per 1,000 sealants/molars. Thus, for the comparison between sealants, ART/HVGIC was cost-effective for the sample data and CR was cost-effective for the projection. In the comparison between sealant methods and STB, in both sample and projection, STB was less cost-effective than both ART/HVGIC and CR.

Table 4.4: Incremental cost-effectiveness results (US2012) for the sample and projection of 1,000 sealants per group after 3 years by treatment group

Intervention	Effectiveness[a], new cavitated dentine carious lesions	Cost	New cavitated dentine carious lesions prevented	Incremental cost	Cost per new cavitated dentine carious lesion prevented
Sample					
CR	11	738			DOMINATED
ART-HVGIC	6	553	6	-185	-37
STB[b]	3	1,346	3	793	264
Projection, 1,000 sealants/group					
ART-HVGIC	84	5,506			DOMINATED
CR	69	5,322	16	-184	-17
STB	41	9,138	27	3,816	140

CR, composite resin; STB, supervised toothbrushing; ART-HVGIC, atraumatic restorative treatment/high viscosity glass ionomer cement. a Effectiveness outcomes are discounted by 3%. b For the STB study, the toothbrushing supervisor went to the schools 180 days per year to supervise the children.

Sensitivity analysis

Given that STB was dominated by the sealant intervention method and the supervision cost accounted for 95% of costs, a sensitivity analysis was carried out to determine how changes in the number of STB days and in the incidence of cavitated dentine carious lesions might affect STB in comparison to the sealant method.

The sensitivity analysis displayed in Table 4.5 shows the impact of variations in personnel supervision and the incidence of cavitated dentine carious lesions on the costs, net costs, and ICERs. For scenario 1 the number of supervisory visits was reduced to 36 (1 per week for 1 year), and the incidence of cavitated dentine carious lesions was increased by about 33%. The number of supervisory visits for scenario 2 was reduced to 9 (1 per month), and the incidence of cavitated dentine carious lesions was increased by about 52%. The impact of the 2 scenarios, if implemented for 1 year in the sample and the projection, resulted in a decrease in costs and net costs for STB in both scenarios. STB was more than 40% less costly than CR, the most inexpensive sealant application intervention in the study sample.

In the incremental cost-effectiveness comparisons with the sample data, STB was compared to ART/HVGIC. STB produced savings of USD 180 in scenario 1 and savings of USD 395 in scenario 2 per new cavitated dentine carious lesion. In the projection sample, when compared to CR, STB experienced savings of USD 273 for scenario 1 and USD 686 for scenario 2 per new dentine carious lesion prevented per 1,000 STB molars.

Table 4.5: Sensitivity analyses: Baseline performance and net costs (USD) for the sample (recorded times), activity sampling data and a projection of 1,000 STB of caries-free molars for the STB scenarios, as well as the results of the incremental cost-effectiveness ratios with the STB scenarios.

Sensitivity Analyses	STB S1 36d/yr	STB S2 9d/yr
Cost per STB molar		
Sample	2.17	0.77
Activity Sampling	2.17	1.55
Projection of 1,000 sealants	1.07	0.72
Net cost[a] STB molar		
Sample	2.71	2.15
Activity Sampling	2.57	1.95
Projection of 1,000 sealants	1.50	1.21

	Effectiveness[b], new cavitated dentine carious lesions	Cost	New cavitated dentine carious lesions pre-vented	Incremental cost	Cost per new cavitated dentine carious lesion pre-vented
STB Scenario 1					
Sample					
CR	11	738			DOMINATED
ART-HVGIC	6	553	5	-185	-37
STB	4	193	2	-361	-180
Projection, 1,000 sealants/group					
ART-HVGIC	84	5,506			DOMINATED
CR	69	5,322	16	-184	-12
STB	55	1,499	14	-3,823	-273
STB Scenario 2					
Sample					
CR	11	738			DOMINATED
ART-HVGIC	6	553	5	-185	-37
STB	5	159	1	-395	-395
Projection, 1,000 sealants/group					
ART-HVGIC	5,506	5,506			DOMINATED
CR	5,322	5,322	16	- 184	-12
STB	1,209	1,209	6	-4,113	-686

STB S1, scenario where toothbrushing supervision takes place weekly, or 36 days over one school year; STB S2, toothbrushing supervision takes place monthly or 9 days over one school year. CR, composite resin; STB, supervised toothbrushing; ART/HVGIC, atraumatic restorative treatment-high viscosity glass ionomer sealants. aNet costs include the cost of STB supervision per molar and restoration if cavitated dentine carious lesions developed. bEffectiveness outcomes are discounted by 3%.

Discussion

As part of a larger community trial, this study reported on the cost-effectiveness of several approaches to preventing the development of cavitated dentine carious lesions on the occlusal surfaces of first permanent molars. It compared the costs of performing sealants as well as the net sealant costs (including adverse events) for 2types of sealants, CR and ART/HVGIC, and the costs and net costs of STB over 3 years. The results of the clinical comparison did not reveal statistically significantly differences between groups after 3 years (11).

Prospective cost data collection and time measurement are study strengths. In addition, the study was carefully carried out in terms of treatment as well as the daily(180days/year) supervisionoftoothbrushingforthe STB group. The differences in the results between the sample data and projection 1 are probably due to the large variation in size of the sample groups compared to the projection groups, which were all the same size. Although the ART/HVGIC group was much smaller in the study sample, when the groups were standardized in the projection, the ART/HVGIC group was the group that ended up with the largest number of failures. The outcome in favor of CR was savings.

The difference between the study times recorded for performing sealants and the activity sampling times may be due to the fact that the number of sealants performed in the study was relatively small, and as a result even smaller numbers of sealants were included in the activity sampling sessions. In addition, the activity sampling included entire sessions that included a variety of clinical and non-clinical activities.

As a limitation of this study, the conceptual framework tested herein did not involve parents as part of changing children's oral health habits through the implementation of regular STB with fluoridated toothpaste. This is an important aspect, as it is known that the entire family should take responsibility for the child's dental hygiene (28). However, the positive clinical results of the present investigation indicate that, most probably, the children kept the habit of brushing at home during weekends, school breaks, and the long summer vacation period (they had to act on their own for 2 months). Another limitation may be that we do not know whether this habit would be established if supervision were to take place 36 or 9 times per year. The projections assume little or no change in the toothbrushing habits and this requires investigation.

Given that this study was conducted in Brazil and aims to inform Brazilian policymakers, its internal validity is very high. In this study, the breakdown of costs by input showed that personnel represented the largest proportion of costs in all 3 groups; it represented 100% of the costs in the STB group. The next highest source of expenditure was instruments and supplies, including dental materials. The prices of dental equipment and materials vary by country, depending on whether they are manufactured in the country or imported. In the case of Brazil, much of the dental equipment is manufactured there so that capital equipment costs may be relatively low compared to other countries. Thus, the study's external validity would probably be low. Although pedodontists performed the sealants, having them replaced by general dental practitioners employed by the ministry of health would reduce the cost to a certain extent.

A study evaluating the cost-effectiveness of sealant materials on occlusal and smooth surfaces in preventing new dentine carious lesions in Wuhan, China (29,30) showed costs that were somewhat lower than those in this study for CR and ART/HVGIC sealants. It is difficult to make comparisons between the results of these 2 studies because their objectives were different and the Wuhan study included sealants on occlusal and smooth surfaces of permanent molars whereas the Paranoá study dealt with sealants on the occlusal surfaces only. This could have affected the time performing the sealants and their costs. One similarity that occurred in the 2 studies was that the cost of CR increased in the projection of 1,000 sealants, while the cost of HVGIC decreased. This may have been related to the cost of capital equipment and declining economies of scale.

The change in direction of cost-effectiveness between ART and CR from the sample to the projection is probably related to standardizing the sample sizes, but it also reinforces the fact that both materials are similar in their effectiveness in the prevention of dentine carious lesions, and both can be cost-effective depending on the circumstances wherein they are used.

The highest costs among the 3 groups in the study sample were for the STB group because the supervision was conducted for 180 days per year. The resulting ICERs for the study sample were too high to be considered affordable. Nonetheless, the sensitivity analyses with the supervising scenarios of 36 and 9 days per year provide an insight into the feasibility and possibilities of this proposition. The affordability of STB could depend on how much supervision will still produce a good result. These possibilities should be explored through further

community research to help guide policymakers and researchers in structuring such a program which would fit into the nation's policy of community-based oral health care.

The impact of STB on caries experience in schoolchildren has been investigated frequently, showing conflicting results. A recent Cochrane review (31) showed that oral health education programs in combination with STB and fluoridated toothpaste may show a beneficial effect on dmfs (low-quality evidence) and dmft (low-quality evidence), but may show little effect on DMFS (low-quality evidence) and DMFT (moderate-quality evidence). This is in discordance with the high caries preventive effect of STB in first permanent molars in the present study after 3 years, which was not significantly different from CR and ART/HVGIC sealants. An important topic for future research is the question "to what extent are the results of the present study related to the high frequency of supervision at schools?"

Another study that investigated the effectiveness of STB in Brazil was carried out on 5-year-old schoolchildren from a low-income area of São Vicente, a small city near São Paulo (32). The author compared a conventional STB program that consisted of oral health education and toothbrushing conducted by dental assistants 4 times per year to a modified STB program, in which dental assistants also taught the children to perform a bucco-lingual toothbrushing technique in (erupting) permanent molars 5 times per year. The results showed that the modified STB program was only effective for boys, who had a higher caries experience at the start. This finding supports the reduced selection of visits by dental assistants in the sensitivity analysis, and the likelihood that the effectiveness of the current STB program will lead to reduced costs and increased affordability.

Over the last decade, Brazil has made a significant investment in developing a national oral health policy, *Brasil Sorridente* or Smiling Brazil, which sought to collect epidemiological data on oral health, the development of dental professionals, and the integration of oral health into its unified health system, *Sistema Único de Saúde* (SUS) (33). As part of this initiative the number of oral health teams (comprised of a dentist, an oral health technician, and/or an oral health assistant) working in primary health care has increased. They work together with the SUS primary care family health teams which consist of a physician, a nurse, a nursing assistant, and a community health worker. In 2015, there were 23,940 such teams in 4,978 cities in Brazil or 1 oral health team in 89.5% of Brazilian cities today (33). The authors describe the Ministry

of Health goal with respect to these teams as being "organized to maintain a balance between individual clinical care sessions and community actions, such as health education, supervised toothbrushing, topical application of fluoride, and atraumatic restorative treatment."

In terms of strategies to tackle inequality in the country, narrowing health gaps by adopting measures aiming to increase health gain among the most vulnerable individuals has already been proposed (34), and the implementation of effective oral health prevention is urgently needed (35). Nonetheless, it is important to consider that, very frequently, good quality public health programs for improving child health are more prone to benefit those who need them least (36). Therefore, the implementation of an STB scheme in schools can be an option for caries control, especially for those who are usually exposed to risk factors in locations where the access to regular preventive care is sporadic. Further, to implement such a strategy requires the involvement of the schools' principals, teachers, and staff, promoting an environment which has already been shown to have a positive influence in their students' oral health status (37).

A further consideration is related to the long-term and shared effects of STB. When applying a sealant, the protection is provided to an individual tooth. By adopting regular good oral hygiene habits all teeth will benefit uniformly and for a long time. It is well accepted that brushing frequently using fluoridated toothpaste is an effective measure to prevent carious lesions development (38). Anopa et al. (39) evaluated the Scotland-wide National Nursery Toothbrushing Program from 1999 through 2009, comparing its implementation costs with the cost savings from improvements in the dental health of 5-year-olds through avoided dental extractions, fillings, and potential decay. They found that the program's implementation costs were less than the savings, which were 2.5 times these costs after 8 years. In addition, the largest cost decrease was among children in the lowest socio-economic income group.

The sensitivity analysis conducted on STB, in both the study sample and the projection, sought to provide additional information regarding how a change in frequency of the application of personnel, the major cost factor, might impact the cost of the intervention. The results of the sensitivity analysis point to the potential cost-effectiveness of an STB program which could be deployed through the schools with the participation of oral health professionals who visit the schools to examine children, as well as providing oral health education and training teachers and perhaps parents to carry out daily STB. Such a program would result in a community-based

preventive approach that would surely contribute to the continuation of the progress the country has made in oral health as well as lower the costs. Other trials have already shown that even people without specific training in dentistry, such as teachers (40) and mothers (41), would be able to successfully perform the STB.

If teachers and parents cannot perform the STB, a viable option in Brazil could be having a member of the SUS primary care family health teams — the oral health assistant or the community health worker, for those areas where the oral health team is not available—responsible for that. According to the National Primary Health Care Policy (42), the legal functions of the oral health assistant as well as those of the community health worker do not conflict with the adoption of an STB program managed by them. It seems reasonable to take some hours of 1 day per week or month, as proposed in the 2 scenarios herein, to visits schools. There would be no relevant extra costs involved in doing this, since the main cost of STB is related to personnel (Table 4.2).

Whilst the STB method investigated in the present study is primarily directed at cleaning medium and large tooth cavities in order to keep them plaque free, the supervision had a spin-off on the cleanliness of the other teeth. Compared to non-supervised children from the CRT and ART group, the visible plaque levels of all teeth in the STB children were significantly lower(43), and although there is no consensus yet about the impact of STB programs on caries development in permanent teeth, such programs become very important in providing toothpaste to young children from low-income areas. There is evidence that its availability on a regular and large-scale basis to the Brazilian market was responsible for the reduction in caries prevalence shown in the last decades (44). Therefore, considering that fluoridated toothpaste is not always affordable for every child in resource-strapped areas of Brazil, such as Paranoá, its simple distribution to Brazilian school children, in association with encouraging a regular toothbrushing habit, is very likely to achieve good results in a high-caries risk population that is not exposed to any other caries preventive measure.

In conclusion, although the results of the sample incremental cost-effectiveness analysis show STB (180 days) as being too expensive and favor ART/HVGIC for the sample and CR for the projection, the evidence of the effectiveness of STB in this clinical trial and the sensitivity analysis point to the value of further research on the benefits of adopting STB as a long-term

venture in the general population of school children. Longitudinal research could explore the uncertainties related to the number of annual visits needed to ensure the habit is solidly adopted and the incidence rate of the development of new cavitated dentine carious lesions wherein the intervention would be cost-effective. The incremental cost-effectiveness analysis showed the difference in the ICERs between CR and ART/HVGIC sealants for the sample and the projection of 1,000 sealants per group to be minimal in relation to one another. CR, being the least expensive option, might be considered an alternative if costs are prioritized, and in efforts to reach larger segments of the population under conditions where dental clinics and equipment are not available, ART/HVGIC, given its portability, might be the preferred alternative.

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Chapter 5

Replacing amalgam with a high-viscosity glass-ionomer in restoring primary teeth: A cost-effectiveness study in Brasilia, Brazil

This chapter by Goldman A, de Amorim RG, Frencken JE, Leal SC, Replacing amalgam with a high-viscosity glass-ionomer in restoring primary teeth: A cost-effectiveness study in Brasilia, Brazil, *J Dent* 2018; 70:80-86.

Abstract

When planning primary oral health care services the cost implications of adopting new intervention practices are important, especially in resource-strapped countries. Although on a trajectory to be phased-out, amalgam remains the standard of care in many countries. Adopting a government perspective, this study compared the costs of performing amalgam and ART/high-viscosity glass-ionomer cement (HVGIC) restorations and the consequences of failed restorations over 3 years in suburban Brasilia, Brazil. Cost data were collected prospectively; cost estimates were developed for the study sample and a projection of 1,000 single- and 1,000 multiple-surface restorations per group. Probabilistic sensitivity analysis was conducted in TreeAge Pro. Results were mixed. For single-surface restorations, ART/HVGIC will cost US$51 per failure prevented, while for multiple-surface restorations, ART/HVGIC was cost-effective with a savings of US$11 compared to amalgam. Probabilistic sensitivity analysis (Monte Carlo simulation) predicted amalgam would be cost-effective 49.2% of the time compared to HVGIC at 50.6% of the time at a willingness to pay of US$237. Personnel accounted for more than half the cost burden for both methods; instruments and supplies accounted for about one third. The per restoration cost to replace amalgam with HVGIC ranges from US$1 to a savings of US$0.84 . Replacing amalgam with a high-viscosity glass-ionomer as part of the ART method comes at a minimal increase in cost for governments. Increasing the number of restorations seems to diminish the cost burden. ART/HVGIC could be considered a viable alternative to amalgam in primary teeth.

Introduction

Following the Minamata Treaty on Mercury recommending a phase down of the use of amalgam, international oral healthcare organizations such as the Federation Dentaire International (FDI) and the World Health Organization (WHO), have called for the development of alternative, biomimetic, restorative materials (1,2). One such material is a restorative glass-ionomer. Its high-viscosity type, in conjunction with the atraumatic restorative treatment (ART) approach, has been shown to produce restorations whose survival is not statistically significantly different from that of comparable amalgam restorations (3) and that of composite resin restorations in primary teeth (4). A recently published study confirmed this conclusion (5).

There have been many studies comparing the effectiveness of amalgam and other alternative restoration methods, however, scant research has been conducted to estimate the potential additional costs associated with making the change from amalgam to other restoration materials. A search of the literature for studies that have investigated this topic in the primary dentition did not yield any peer review articles.

While the international phase down of the use of amalgam entered into force 16 August 2017 (6), it is expected and perhaps accepted, that the rate of change over will vary from country to country — with resource (technical and financial) strapped countries being the last to implement the recommended change. Within countries, the communities that would be the last to have these changes implemented are poor and usually rural communities. In implementing programs geared toward facilitating a transition from amalgam to other materials, such as high-viscosity glass-ionomer cement (HVGIC), dental program developers, will be most interested in not only in comparative effectiveness, but also in other factors such as: needs for additional technical and administrative resources and the potential cost of additional equipment needs.

This study presents an analysis of the costs associated with switching from amalgam to high-viscosity glass-ionomer ART restorations for the primary teeth in a randomized clinical trial that compares the effectiveness of amalgam and high-viscosity glass-ionomer ART restorations amongst school age children in Brasilia, Brazil. This cost-effectiveness analysis sought to: (i). determine the mean time spent, for each intervention protocol, in carrying out single- or multiple-surface restorations; (ii) assess the costs and net costs associated with the

placement of restorations for each intervention protocol, amalgam and ART/high-viscosity glass-ionomer (ART/HVGIC); (iii) conduct an incremental cost-effectiveness analysis comparing amalgam to high-viscosity glass-ionomer (HVGIC) as a restoration material; and (iv) determine how changes in cost inputs for each method affect the cost of the restorations and the cost-difference of switching from amalgam to high-viscosity glass-ionomer. The study time horizon was 3 years.

Methods

Community effectiveness trial

The restoration trial was approved by the Research Ethics Committee of the University of Brasília Medical School (reference number 081/2008) and was registered at the Dutch Trial Registration Centre (reference number 1699). Parents and/or caregivers were informed in writing about the investigation and treatments. Children whose parents or caregivers completed and signed the consent forms were included in the study. Details of the study were published previously (5) and a summary of it is provided below.

The randomized clinical trial used a parallel study design and was carried out amongst 6- and 7-year-old children from a low socioeconomic area of Brasilia, the capital of Brazil. Inclusion criteria were: good general health and having at least two cavitated dentine carious lesions in vital pain-free primary molars assessed according to the ICDAS II system. The study groups consisted of three protocols: conventional restorative treatment (CRT), where amalgam restorations were applied; ART, high-viscosity glass-ionomer restorations (HVGIC); and, Ultra-Conservative Treatment (UCT) which included the cleaning of medium and large cavities to maintain them plaque free under the daily supervision of one of the dental assistants during school time, and restoring small cavities that are difficult to clean according to ART.

Treatments were performed on the grounds of six primary schools by three trained pedodontists, assisted by trained dental assistants. The CRT protocol was performed in a dental clinic that was available in two schools, using rotary equipment and the cavities were restored with a high-copper non-gamma2 spherical and lathe cut amalgam (Permite Regular set®; SDI,

Melbourne, Australia). The ART restorations were performed in the two ART schools and the two UCT schools, in rooms where each participating child lay on a mobile bed with artificial light, according to the instructions by Frencken *et al.* (7). The restorative material used was Ketac Molar Easymix® (3M ESPE, Seefeld, Germany).

Two trained, calibrated and independent evaluators (dentists) assessed the restorations in the primary teeth according to the ART restoration criteria (5) on the school premises after 6 months, 1, 2 and 3 years. Secondary caries was defined as an obvious cavitated dentine carious lesion. Battery-illuminated dental mirrors (Kudos®, Hong Kong, China), CPITN probe Golgran) and compressed air aided the evaluation. Re-restoration of primary molars was carried out for cases where secondary dentine carious lesions were found. During the study period, restored teeth that caused pain and were not considered viable were extracted. For the most part, in cases of mechanical failure if part of the restoration remained, the teeth were considered viable and the child was not experiencing pain the restorations were left alone and the teeth exfoliated naturally.

Because the researchers did not find a statistically significant difference in cumulative survival percentages between ART/HGVIC restorations cleaned under the UCT supervised tooth brushing protocol and the ART group ($p = 0.16$), the two groups were combined into one ART/HGVIC group [5] in the effectiveness study. This study compared the cumulative survival percentages of restorations in the primary teeth using amalgam (CRT) and a high-viscosity glass-ionomer cement (HVGIC; applied in the ART and UCT groups) in primary molars over a period of three years. The baseline intervention and results over three years are presented in Table 5.1.

The cumulative survival percentage for all amalgam restorations in the effectiveness study was 72.6% compared to 66.8% for all ART/HGVIC restorations after 3 years; this difference was not statistically significant (5). After three years, the single-surface restorations under both treatment protocols had higher survival percentages than the multiple-surface restorations. Ten secondary dentine carious lesions developed under both treatment protocols; in each case more than half occurred in multiple-surface restorations. The total number of extractions under both protocols was 34; 19 for amalgam and 15 for ART/HVGIC.

Table 5.1: Survival (SE) of amalgam and ART/HVGIC restorations by type in the Paranoa trial, reasons for failure (secondary dentine carious lesion or mechanical failure), and probability of failure (95% CI).

	All restorations		Single-surface		Multiple-surface	
	Amalgam	**ART/HVGIC**	**Amalgam**	**ART/HVGIC**	**Amalgam**	**ART/HVGIC**
Children (N)	126	154				
Schools (N)	2	4				
Restorations by type (N)	364	386	105	116	259	270
Mechanical failure (N)	79	105	4	8	75	97
Secondary dentine carious lesion (N)	3	7	1	2	2	5
Extractions	19	15	1	2	18	13
Survival at 3 yr %(SE)	72.6 (2.9)	66.8 (3.1)	93.4 (3.3)	90.1 (3.0)	64.7 (3.6)	56.4 (3.9)
Probability of failure (95%CI)	0.2749 (0.217-0.330)	0.332 (0.271-0.393)	0.066 (0.001-0.131)	0.099 (0.04-0.158)	0.353 (0.282-0.424)	0.436 (0.360-0.512)

SE = standard error; ART /HVGIC = atraumatic restorative treatment/high-viscosity glass-ionomer cement

Cost-effectiveness analysis study design

The study adopts a government program perspective and seeks to provide information on the inputs, their effects and the costs that go into the implementation of each dental caries prevention and care intervention protocol. This information can enhance each entity's capacity to maximize the use of available resources in planning and implementing the intervention protocol that is most feasible to them.

The study outcome was evaluated in two ways: counting the total number of teeth with failed restorations in each group, and counting only the number of restored teeth that developed a cavitated carious lesion or were extracted over the 3-year period. The adverse effects costs include the cost of re-restoring teeth where secondary dentine carious lesions developed, as well as the costs of extractions. Restored teeth that exfoliated naturally and those that had mechanical failures but were judged viable were not included in the second analysis.

Outcomes and costs, including the costs of adverse events, i.e., re-restorations and extractions estimated in the study, were discounted at a rate of 3% (8). Cost data were recorded in Brazilian *reais* (R), adjusted for inflation using the World Bank GDP inflation deflator and then converted into 2012 US dollars (9).

The intent of this study is to inform dental practitioners and oral health program planners and policy makers and enhance their ability to evaluate the broader consequences and opportunities of replacing amalgam with the alternative of high-viscosity glass-ionomer cement for the care of dental caries in the primary and permanent dentition of young children as they go through an important period in their oral health development. To that end, the analytic study was expanded beyond the study population used in the effectiveness study trial, to include analysis of a projection sample of 1,000. This will provide information for making the change on a larger scale than for the study group.

Data collection: Personnel time

Personnel time is a fundamental element to estimating the costs of interventions. Data were collected in two ways to estimate personnel time during the intervention. In the first instance the assistant recorded the actual start and end time for each restoration performed in every

intervention session. In the second, a systematic method was used to sample several sessions to obtain estimates for the restoration times as well as other activities not captured in the recording of the actual time method.

Actual time method: The assistant recorded the start and end time for placing each restoration. The start time began when the pedodontist's instruments were lifted to start the restoration and ended the moment they finished and put down the instruments.

Systematic sampling method: The systematic sampling method used in this study is referred to as activity sampling (10) time as it serves to capture, as best possible, all activities that occurred during the entire session, in addition to restoration placement.

Of the 66 4-hour sessions that were covered in the actual time data recording, only 35 were included in activity sampling data collection. The method was implemented by sampling the 4-hour treatment sessions in 15-minute intervals using a countdown timer. In an effort to capture activities at varying times during the sessions, the timer was set at a different time after the session began (usually 8:00 am) each day. The number of minutes after 8:00 am was determined by the last number in the identification number of the first child treated that day. The timer sounded at each 15-m interval and the assistant recorded the code that best described the pedodontist's activity at that moment. For example, if the pedodontist was performing a restoration in the amalgam group during the second interval, the assistant would write the code for that activity in the space for that time interval.

Clinical activities included exam and diagnosis, placing a restoration, performing an extraction, etc. Complementary activities included preparing the clinical area, instrument preparation, awaiting a patient, or talking with a patient to calm their nerves. Patient absence, equipment failure, dentist absence and other reasons such as coffee break were recorded as other, non-clinical activities. Activity sampling time provided the capacity to better understand the wider range of activities that occured during the session for each of the intervention methods.

Cost data collection

Cost data were collected prospectively. This is a financial analysis. Thus, all costs were recorded, regardless of whether items were purchased or donated. A Microsoft Excel (2013) data collection instrument was created for the study and given to the principal investigators

to fill out. The quantities and costs of instruments and supplies used were recorded by group. Data on the costs of equipment, personnel salaries and the pedodontists' transportation costs were obtained from the records of the University of Brasilia and apportioned by group based on the number of interventions performed in each group. Capital equipment and instrument and materials costs were obtained from actual expenditures; the costs of the dental equipment were annualized. In the case of capital items that were not acquired, the replacement cost was used. The costs of items acquired outside of Brazil such as the ART instruments, which were donated, were priced in euros and converted to *reais*.

Anesthesia was used in the CRT and ART/HVGIC interventions and the cost was calculated separately, utilizing information on the costs of the supplies and the number of times it was used for each group.

Data recording and analysis

The data from the recording of the individual procedure times (actual time method) for both single- and multiple-surface restorations during each of the treatment sessions were included in the study's main database and analyzed using SAS to produce mean times for performing for single- and multiple-surface restorations and their standard errors (SEs). In addition, the times of both the single- and multiple-surface restorations were combined to estimate an overall mean time per restoration for each intervention method.

The activity sampling time data (activity sampling time method) were entered into an ACCESS database by one person and verified by a second. The data were transposed into and analyzed in SAS® 9.3 (SAS Institute, Cary, NC, USA) to obtain mean times per session. The proportion of time consumed by clinical and other, non-clinical activities in each session, for each intervention method was calculated. The time for performing restorations was divided by the number of restorations per session to obtain a proportion. This proportion was used to calculate the time it took to perform each restoration.

The mean number of minutes it took to perform a single- or multiple-restoration for each intervention group was converted to hours. The pedodontists worked in 4-h sessions, approximately 66, representing about 264 hours. The proportion of time dedicated to each

activity by group, was used to approximate the number of hours for each intervention group; close to 121 hours for CRT, 77 hours for ART, and 66 hours for the UCT group. The difference between total treatment time and the total number of hours per method was apportioned to each procedure in coming up with an overall per unit cost.

To calculate the proportion of time it took to complete the baseline intervention, the time the operators took to complete the intervention was estimated to be 4.5% of a year. This proportion was applied to the cost of the annualized equipment for sample costs.

Costs and incremental cost-effectiveness analysis

Once the mean times were obtained from the actual time data, the value of personnel time per minute was calculated by multiplying the value of salary time per minute by the number of minutes to produce a cost per single- and multiple-surface restoration for the amalgam intervention method and for the combined ART/HVGIC intervention method. The value of personnel time per minute was calculated using salary data. The costs of single- and multiple-surface restorations performed for each treatment group were averaged to calculate one cost for all amalgam and one cost for all ART/HVGIC restorations. Because the activity sampling time data only captured whether an amalgam or ART/HVGIC restoration was done, and not whether they were single- or multiple-surface restorations, the costs per restoration for the activity sampling data are averages for all amalgam and ART/HVGIC restorations.

For the incremental cost-effectiveness analysis, the differences in the costs and outcomes between the amalgam and ART/HVGIC study groups are evaluated in a ratio where the difference in costs is divided by the difference in outcomes (11, 12). As ART/HVGIC is one of the candidate approaches to replace amalgam, the ratio provides information about what additional costs will be incurred using ART/HVGIC to prevent one additional failure.

Projection Sample

The results for the sample are presented alongside a projection of production of 1000 single-surface and 1000 multiple-surface restorations for each method. To create the projection, inputs such as personnel time, instruments and supplies were increased at the same rate as in

the original sample. The production of a much larger number restorations in the projection would be expected take longer than 4.5% of a year. The estimate was closer to about 25% of a year and was applied to the projection.

Sensitivity analyses

The impact of increasing the costs of personnel time alone and in combination with the costs of instruments and supplies (5% to 20% change) on the net cost per restoration was explored in sensitivity analyses. To increase the cost, the proportion of the total cost of a restoration represented by a particular input, 57% in the case of personnel, was subtracted from the total cost per restoration and multiplied by the increase proportion and added to the total. Changes in the cost of HVGIC (25% increase and 25% decrease) and their effect on the cost difference between the sample size groups were also evaluated.

A probabilistic sensitivity analysis (PSA) was conducted to create a cost-effectiveness acceptability curve to evaluate the cost-effectiveness of the two strategies given a willingness to pay (WTP) threshold for a gain in preventing one additional failed restoration. The WTP threshold chosen orginated in 1993 World Bank recommendations for a minimum health package where interventions valued at US$150 per DALY or disability adjusted life year, were considered acceptable for low-income countries (13). The DALY has been used by nations, international organizations (such as the World Bank and the WHO), as well as academics, to measure health status globally.

To conduct the PSA, a model comparing amalgam and ART/HVGIC was built in TreeAge Pro 2017 (14) using data derived from the study. A Monte Carlo simulation of 10,000 bootstrap re-samples was run. Lognormal distributions were used for costs and effectiveness; beta distribution was applied to probabilities. The WTP threshold of US$150 in 1993 was adjusted to US$237 in 2012.

Results

Time to perform restorations

As is shown in Table 5.2, for all types of amalgam restorations performed the actual mean time and the activity sampling mean time were similar. The ART/HGVIC activity sampling mean time was 2.6 minutes more than the actual mean time. With respect to placing single-surface restorations the mean time for ART/HGVIC was 10 minutes, 2.4 minutes more than that for amalgam. However, for multiple-surfaces the mean performance time for ART/HGVIC was shorter by 0.7 minutes.

Cost per restoration

The costs per restoration performed using actual time in Table 5.2 show that the cost for doing all restorations was comparable for ART/HVGIC and amalgam; ART/HVGIC cost US$0.08 more than amalgam. ART/HVGIC cost US$1.00 more than amalgam per single-surface restoration. With respect to multiple-surface restorations, the cost for ART/HVGIC was US$0.84 less than for amalgam. In the case of all restorations performed using ART/HVGIC calculated with the activity sampling time the cost was $1.01 higher than the cost calculated with actual time. Similarly, the activity sampling time cost for amalgam was US$0.95 higher.

For the projection of 1,000 of each category of restoration, all costs were lower than for the sample and the pattern was similar. For the total of all ART/HGVIC restorations the difference was $0.17 per restoration, for single-surface restorations, the difference was $0.90. Multiple-surface restorations performed with amalgam were US$0.55 more than ART/HVGIC.

Table 5.2: Mean time (min (SE)) for performing amalgam and ART/HVGIC restorations for the sample with actual and activity sampling data, and costs and net costs (US$ 2012) per restoration for actual and activity sampling time per restoration method for the sample and the projection data, respectively

	Treatment protocols					
	Amalgam			ART/HVGIC		
Mean time (min(SE)) for performing restorations	**All**	**Single**	**Multiple**	**All**	**Single**	**Multiple**
Actual time	13.6 ± 0.4	7.6 ± 0.3	16.0 ± 0.4	13.7 ± 0.3	10.0 ± 0.3	15.3 ±0.3
Activity sampling time	13.4 ± 1.8			± 1.3		
Cost per restoration performed						
Actual time (sample)	10.15	7.92	12.38	10.23	8.92	11.54
Activity sampling time (sample)	11.10			11.24		
Projection, 1000 restorations of each type	7.69	5.57	9.80	7.86	6.47	9.54
Net cost per restoration						
Actual time (sample)	10.63	8.10	13.15	10.39	9.07	11.71
Activity sampling time (sample)	11.70			11.95		
Projection, 1000 restorations of each type	8.03	5.66	9.84	8.41	6.79	10.03

Min = minute; SE= standard error. ART /HVGIC = atraumatic restorative treatment/high-viscosity glass-ionomer cement. Net costs include the cost of performing a restoration plus adverse events costs. Restoration categories: all, single- and multiple-restorations. Projection: 1,000 of each type of restoration. All refers to the mean for all single- and multiple-surface restorations for each treatment protocol.

Net costs per restoration for the sample using actual time and for the projection, also shown in Table 5.2, followed a trend similar to that of performance costs. The differences in the net cost values, across the board, for both amalgam and ART/HVGIC, for all categories of restorations were comparable to those obtained for performing restorations.

Breakdown of inputs

The breakdown of inputs in Table 5.3 shows that personnel consumes the largest percentage of resources in the sample groups — 57% for both groups, followed by instruments and supplies, 32% for amalgam and 39% for ART/HVGIC. Equipment represented 4% of the amalgam group compared to 0% for ART/HVGIC.

Table 5.3: Breakdown of inputs as a proportion of intervention costs for restorations for the amalgam and the ART/HVGIC groups.

	Treatment protocol	
Input	**Amalgam**	**ART/HVGIC**
Personnel	0.57	0.57
Instruments and supplies	0.32	0.39
Equipment	0.04	0.00
Transportation	0.03	0.03
Anesthesia	0.04	0.01

ART = Atraumatic Restorative Treatment; HVGIC = high-viscosity glass-ionomer cement

Incremental cost-effectiveness

The results of the incremental cost-effectiveness analysis are presented in Table 5.4. Including all of the failures in restored teeth in the incremental cost-effectiveness ratio (ICER) comparing ART/HVGIC to amalgam in the study sample resulted in a savings of USD $1.44 per failure prevented for all restorations, a savings of USD $11 per failure prevented for multiple surface restorations and a cost of USD $51 for single surface restorations. In the projection, the cost per failure prevented for all restorations increased to USD $6, while the cost per single surface amalgam restoration was reduced to USD $29. The only cost savings was USD $5 per failure prevented per multiple surface restoration. The additional cost or savings per

restoration performed followed a pattern similar to that of the ratio for both the sample and the projection ranging from savings of USD $11 to a cost of 2 dollars per restoration.

When the analysis considered only those failures that incurred additional costs in the sample — e.g., the failed restorations that developed dentine carious lesions and required re-restoration and the molars with restorations that had to be extracted — the ratio for all restorations could not be obtained, because both groups had the same outcome of 22 re-restorations and extractions and the difference in outcomes was 0. This was not the case for the single-surface restorations where the cost per failed restoration was USD $101 or the multiple-surface restorations where the cost per failed restoration was USD $123. The ICERS for the projection for the failures incurring additional costs resulted in an additional cost of USD $15 per additional failure for all restorations, a cost of USD $40 per additional failure per single-surface restoration, while per multiple-surface restoration, the savings was USD $15. The additional costs per restoration performed were the same as for the analysis for all failures.

Sensitivity analyses

There were no major differences when the cost of personnel was increased in 5% increments up to 20%; the increases resulted in a net cost increase of US$1.19 per ART/HGVIC and US$1.16 per amalgam restoration for the recorded sample data. When similar increases were applied to the costs of both personnel and instruments and supplies for the sample the net cost per ART/HVGIC restoration went up by US$1.98 while the net cost per amalgam restoration went up by US$1.72.

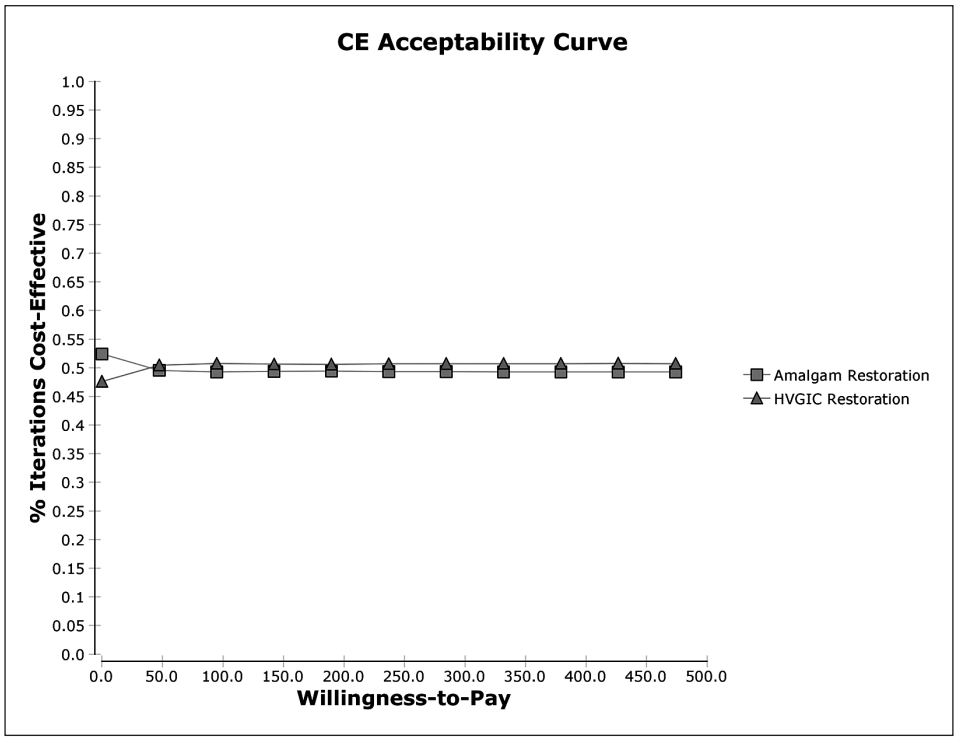
The trend for cost increases in personnel and personnel and supplies in the projection of 1,000 single- and 1,000 multiple-surface restorations was similar. For personnel, the overall increase in net cost of US$0.75 per ART/HGVIC and amalgam restoration. The net cost increases for both personnel and instruments and supplies were US$1.44 per ART/HVGIC restoration and US$1.23 per amalgam restoration.

Table 5.4: Cost (USD) per additional failure prevented of ART/HVGIC compared to amalgam in restorations in the primary dentition, for all restorations, single-surface restorations and multiple-surface restorations, and additional cost or savings per ART/HVGIC restoration performed.

	Total outcomes	Total cost	Failures prevented	Cost difference	Cost/savings (-) per failure prevented
All failures, including restored teeth that eventually exfoliated naturally					
Sample: All					
Amalgam	82	4,257			
HVGIC/ART	112	4,214	30	- 43	- 1.44
Single-surface					
Amalgam	4	851			
HVGIC/ART	8	1,053	4	51	51
Multiple-surface					
Amalgam	75	3,407			
HVGIC/ART	97	3,162	22	- 11	- 11
Projection: All					
Amalgam	451	16,058			
HVGIC/ART	580	16.814	130	756	6
Single-surface					
Amalgam	48	5,663			
HVGIC/ART	86	6,788	38	1,125	29
Multiple-surface					
Amalgam	297	10,395			
HVGIC/ART	378	10,026	80	369	-5
Only failures incurring additional costs (re-restoration and extraction					
Sample: All					
Amalgam	22	4,257			
HVGIC/ART	22	4,214	0	-43	0
Single-surface					
Amalgam	2	851			
HVGIC/ART	4	1,053	2	202	101
Multiple-surface					
Amalgam	20	3,407			
HVGIC/ART	18	3,162	-2	-245	123
Projection: All					
Amalgam	89	16,058			
HVGIC/ART	140	16.814	51	756	15
Single-surface					
Amalgam	12	5,663			
HVGIC/ART	40	6,788	28	1,125	40
Multiple-surface					
Amalgam	77	10,395			
HVGIC/ART	99	10,026	22	- 369	- 16

Failures defined as restorations placed in primary molars that later developed dentine carious lesions and required re-restoration, or those restorations scored as mechanical failures that required extraction. ART/HVGIC, atraumatic restorative treatment/high-viscosity glass-ionomer cement.

Figure 5.1: Cost-effectiveness acceptability curve comparing amalgam and ART/HVGIC
This curve illustrates the probabilistic sensitivity analysis results and shows the percentage of times each approach was cost-effective given the willingness-to-pay threshold of US$237 per failed restoration prevented.



The Monte Carlo simulation results showed that at the WTP threshold of US$237 amalgam was cost-effective 52.27% of the time, compared to ART/HVGIC 47.67% of the time. In Figure 5.1, the CEAC produced by the simulation shows that after 10,000 re-samples HVGIC tended to be cost-effective about 50.6% of the time, while amalgam was cost-effective about 49.2% of the time.

Discussion

Although on a trajectory to be phased-out, amalgam is still the standard of care in many countries so it is useful to understand the cost implications of switching to other materials. The results of the effectiveness study showed that the cumulative survival percentages for ART/

HVGIC and amalgam were not statistically significantly different over the three years for all, single-, and multiple-surface restorations (5).

Given the history of improvements in high-viscosity glass-ionomer cements and their improvements in survival to date, it is possible that further advances will continue to increase the survival percentages of HVGIC restorations — thus, improving their effectiveness — in comparison to amalgam and other materials. Recently published clinical studies that have used the new HVGIC, Equia System, showed a 4-year survival percentage of single-surface HVGIC restorations of 98.8% (15) and 100% (16) and of multiple-surface HVGIC restorations of 90.0% (15) and 93.4% (16). Although these studies were performed in permanent teeth, which usually show higher survival percentages than for comparable restorations in primary teeth, the findings appear to be very promising to also reduce the failure rate of HVGIC restorations in primary teeth.

With respect to the time it takes for completing a restoration, ART/HVGIC takes longer for single-surface restorations but the difference disappears with multiple-surface restorations. The reasons for this difference in times are unclear. For the single-surface restorations they could be related to the fact that the removal of carious tissues with the drill is faster than with hand instruments (17). Nonetheless, what should be taken into account is that the drill is much more invasive than the use of hand excavators which preserve more sound tissue.

In terms of the cost and net cost for ART/HVGIC restorations versus amalgam there is little difference in the costs — but for multiple-surface restorations ART/HVGIC is less costly than amalgam.

Personnel was the major cost driver in this study. Personnel costs might be reduced if, rather than using a pedodontist, the restorations are performed by a public health dentist. An even further reduction in costs could be brought about if well trained dental therapists do the work (18).

The result of the incremental cost-effectiveness analysis shows that implementing the ART/HVGIC approach represents an additional investment or savings per failure prevented depending on the type of restoration performed that falls within the WTP threshold of US$237 per failure prevented. The sensitivity analyses conducted underscored the similarity in the costs of performing amalgam and ART/HVGIC restorations.

In their illustration of the usefulness of CEACs, Fenwick and colleagues (19) refer to the degree of uncertainty in cost-effectiveness analyses because of imperfect information on the effectiveness of the intervention and the resources consumed for treatment. A probabilistic sensitivity analysis explores the probability that a technology will be cost-effective and provides additional information to the decision-maker (19). The PSA used in this study translated the uncertainty in the input parameters and provided evidence both approaches could be cost-effective. According to Claxton and colleagues (20) a key advantage of PSA is that, by quantifying decision uncertainty, it can help prioritize future research. Thus, one could conclude the results of the PSA support continuing evaluation of ART/HVGIC as a viable alternative to amalgam.

When the projection of 1000 single- and multiple-surface restorations was created for each treatment method — the result was a decrease in the overall cost and net cost for carrying out restorations for both treatment methods. The amalgam restoration method benefited most from the cost savings brought about by increases in the economies of scale.

It is important to note that dental equipment and materials costs vary depending on whether these items are imported or produced locally. Much of the dental equipment and supplies used in Brazil are produced there. This will affect the costs of the procedures and consequently differences in costs between the restoration protocols.

The prospective derivation of cost data in the present study from an actual clinical trial is a study strength. The fact that the cost and net cost values estimated using the activity sampling time data closely match those calculated using actual data recorded by the attendants, serves to authenticate the use of the actual values in costing. Although the results differed in magnitude, evaluating the groups for all failures and only those that incurred additional costs, showed similar trends in terms of costs per failure prevented.

The trial's short time horizon may be a limitation with respect to costs and effectiveness, but efforts to follow the children after three years were complicated by the structure of the school system and the mobility of low income populations in some areas. Nonetheless, the results in three years do provide the needed information as to the success of the intervention when viewed in the context of the process of exfoliation going on during this period.

There are two items that should be taken into account in terms of the extrapolation of

the findings of this study. One is that the study only included 6-7-year olds, the youngest age group in the school, and school oral health (including sealants) programs would target older children as well. The other is that the only re-restorations in the study were performed to address the development of secondary dentine carious lesions. In addition, it should be noted that 75.9% of the material-related defective restorations survived (21)

Conclusions

There are small differences between the cost and net cost of ART/HVGIC or amalgam restorations in this school study population. Restoration performance, using, ART/HVGIC takes about 2 minutes longer for single-surface restorations; this difference narrows with multiple-surface restorations. ART/HVGIC is less costly than amalgam when performing multiple-surface restorations; why, is unknown.

The projection of 1,000 restorations of each type shows that in a larger population the cost and net cost for placing restorations for both treatment methods can decrease. Personnel accounts for over 50% of the cost associated with ART/HVGIC or amalgam and a 20% increase in personnel and personnel and supplies for both ART/HVGIC and amalgam in the projection showed a less than US$2.00 increase in cost. Thus, there is value to continuing to investigate ART/HVGIC as a viable alternative to amalgam.

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Chapter 6

General discussion, conclusions, and recommendations

Methods

This PhD thesis investigated the costs and cost-effectiveness of key oral health primary care prevention and curative practice measures targeting school age children. The prevention effectiveness studies evaluated in this PhD thesis were carried out as part of school-based community trials in Wuhan, Hubei Province, China and Paranoá, Brasilia, Brazil. The intervention practices evaluated including supervised toothbrushing with fluoride toothpaste, dental sealants, and restorations, sought to prevent the development of cavitated dentine carious lesions and promote natural exfoliation.

The intended audiences for the studies in this PhD thesis are national and regional policymakers, in-country public program service planners and individual private practitioners. The work serves to inform public decision makers interested in developing cost-efficient equitable programs that promote and protect the oral health of all children. Its findings on costs, cost-effectiveness and cost drivers will enhance stakeholders' capacity to maximize the use of their available in-country resources. Its findings are most valuable for oral health decision makers in lower- and middle-income countries with limited resources and a higher proportion underserved populations.

The cost-effectiveness studies estimated the costs and cost-effectiveness associated with different sealant materials and in school children in China in the prevention of cavitated dentine carious lesions in the permanent molars and sealants, and restorations and supervised toothbrushing in preventing cavitated dentine carious lesions and promoting natural exfoliation in the mixed dentition of school children in Brazil. Cost and effectiveness data were analyzed in using incremental cost-effectiveness analysis to determine the cost per cavitated dentine carious lesion or restoration failure prevented. Uncertainty in the data and its influence on the cost- outcome values of each intervention approach was explored through variation in the values of certain inputs, such as the probability of disease incidence or failure, or the costs of personnel, instruments and supplies, etc.,. The study report also provides information on the costs and benefits of switching from amalgam to ART/HVGIC.

Two meaningful elements taken into consideration in the construct of the studies reported here were; (i) how to illustrate evaluation of the effectiveness and cost outcomes at

a larger scale, given that dentine caries prevention effectiveness studies were carried out on a relatively small samples when the intent of these studies was to inform larger programs, and (ii) given its focus on lower- and middle-income countries with limited resources — how could the cost-effectiveness of the programs studied in this PhD thesis be interpreted within a context of what governments might be willing to pay for them. These concerns prompted the creation of projections for each of the studies and the identification of a ceiling or threshold of what governments might be willing to pay against which to make some of the comparisons. The one chosen for the studies in this PhD thesis follows World Bank recommendations for a minimum health package in 1993 in which interventions valued at US$150 per DALY were considered acceptable for low-income countries. Another measure that could have been used (3) is one that sets the threshold at two times the country's annual per capita income. Given the gaps in economic inequality and the uneven development of health programs in countries that are growing quickly like China and Brazil, such a threshold might be higher than what these countries are willing to pay and can pay.

The findings of the studies presented in this thesis are meant to identify potential for more research that serves to highlight cost savings to be had from implementing cost-effective oral health primary care intervention strategies. In addition, it serves as a resource for countries with ongoing programs seeking ways to improve the efficiency and productivity of their current oral health intervention prevention programs.

Findings

Wuhan, China sealant study

1. Both high-viscosity glass-ionomer cement and composite resin had similar outcomes in terms of preventing cavitated dentine carious lesions, both exceeded 95%.
2. At two years, the incremental cost-effectiveness ratio in the Wuhan study seemed to indicate that composite resin was the most cost-effective material because, although LED thermocured ART/HVGIC had better results, it was more expensive and the difference in the number of dentine carious lesions prevented between the groups was very

small. In addition, the two-year time period was really too short for a cost-effectiveness analysis. Nonetheless, sensitivity analyses indicated that this could change over time. After four years the effectiveness of the sealants was still high for both the ART/HVGIC and composite resin groups (over 96%) where the results pointed to LED thermocured ART/HVGIC as being slightly more effective and, while still more expensive, cost-effective compared to composite resin.

3. The ICER for the sample, US$115 per cavitated dentine carious lesion prevented in the actual sample, fell well below threshold of US$226 per DALY (USD 2010), as did the projection of US$52 per dentine carious lesion prevented over 1,000 performed.
4. These results study point to the viability and the effectiveness of glass-ionomer cements if these are used in population based programs.

Paranoa, Brazil study

Sealants

1. The effectiveness of the sealants in the Paranoá sealant study was also high, over 90%. And the incremental cost-effectiveness ratios ART/HVGIC and composite resin sealants flipped from favoring ART/HVGIC at a savings of US$37 in the sample to favoring composite resin with a savings of US$17 in the projection. Both results fell well within the threshold, which in 2012 dollars is US$237 per DALY.
2. The most positive result in the Paranoá study was the result of the supervised toothbrushing group (STB) where no new cavitated dentine carious lesions developed over a period of three years. The costs of STB in the study, 95% personnel costs, were prohibitively expensive for a large scale program; the supervisor went to the schools every day during the school year, at least 180 days. This prompted sensitivity analyses to explore the possibility of reducing the number of times the supervisor went to the schools during the school year. Assuming similar high results, the sensitivity analyses point to the program's viability with a reduced number of supervision days.
3. The results of the sensitivity analyses point to the importance of conducting further research.

4. These conclusions prompted discussion highlighting the potential for integrating STB into the schools as part of national oral health policy and with the aim of increasing oral health gains among the most vulnerable individuals.
5. The concern that small margins of difference between ART/HVGIC and composite resin might be affected by sample size was borne out in this study, when the cost-effectiveness results flipped from ART/HVGIC to composite resin in the Paranoá sealant projection. This outcome demonstrated the value of the projection in that they standardized group sizes were the same as well as how close the two materials are in costs and effectiveness.

Restorations

1. The overall costs of ART/HVGIC and amalgam restorations are similar in the Paranoá study.
2. Costs for single-surface restorations were lower than for multiple-surface restorations.
3. The difference in costs to perform HVGIC and amalgam restorations ranged from US$0.08 more than amalgam for all single- and multiple-surface restorations combined to US$1.00 more per single-surface HVGIC restoration. Amalgam multiple-surface restorations cost US$0.84 more per restoration than HVGIC restorations.
4. Performance time for single-surface restorations was longer for ART/HVGIC than for amalgam.
5. Personnel costs were a major cost driver for both groups — 57% of the total.
6. The incremental cost-effectiveness analysis comparing the two approaches showed that using HVGIC represented a cost savings per restoration failure presented for all and multiple surface restorations while it would cost up to US$123 per multiple surface restoration failure prevented. Nonetheless, that costs fell within the chosen threshold of US$237 per failed restoration.
7. Probabilistic sensitivity analysis showed both approaches had the potential to be cost-effective and given the eventual phase-down of amalgam, exploring the potential of ART/HVGIC is worthwhile.

General Discussion

As one considers different approaches to the delivery of primary oral health care services meant to protect the growth and development of the molars in children, some important findings have emerged from these cost-effectiveness studies. In the Wuhan and Paranoá sealant studies ART/HVGIC, a relatively new care approach and restorative material were compared to the standard of care, composite resin. While all sealant materials displayed a high level of viability, the LED thermo-cured ART/high-viscosity glass-ionomer has the advantage that it can be delivered as a mobile service which expands its capacity of reaching all members of the population in countries struggling with limited access to oral health care. Its ease of application in terms of minimal technical and infrastructure resources needs, combined with cost-effectiveness, make LED thermo-cured ART/high-viscosity glass-ionomer a viable option with economic appeal to capital deprived countries and general settings of resource scarcity. The relatively low loss of children in the Wuhan study over four years points to the viability of a strategy that targets children in the schools.

ART is increasingly being taught in dental schools so that the component of getting used to applying a new material properly, will in time be less of an issue of concern. As practitioners become used to working with glass-ionomers the times to perform sealants and restorations will no doubt decrease. ART training programs are as portable as the treatment programs in that they require instruments and supplies and no capital equipment other than an LED thermo-curing light.

The supervised toothbrushing results confirm that this is an effective method for dental caries prevention for the permanent molars. In addition, it offers an opportunity for generalized caries prevention in the mouth affecting all teeth, including those affected by cavitated dentine carious lesions. The expansion of the family health teams in Brazil, to include dentists and create an oral health promotion community health worker program holds promise. Linking school based supervised toothbrushing initiatives to the family health teams could amplify their reach. Depending on the structure of the school-based programs, these could involve family members, thereby extending program impact into the children's homes. In an effort to evaluate the effectiveness of a community health worker program for oral health promotion,

community health workers and mothers, belonging to the population the community workers serve, were surveyed. The results showed that after the training the reported frequency of toothbrushing and flossing increased in both groups of women (4); they were more confident of their knowledge and its application. In addition, their access to and use of oral health services increased.

One commonality in the sealant studies is the comparison of the conventional treatment approach, composite resin, and the ART approach, which uses HVGIC. The effectiveness of both materials was similar in the two studies, and the differences in lesions were sufficient to produce an incremental cost-effectiveness ratio in both cases after four years in China and three in Brazil. The costs in the Chinese study ranged from being slightly lower to half the cost for the composite resin and ART/HVGIC sealants, respectively. The cost of performing a composite resin sealant was US$2.95 and ART/HVGIC sealant at baseline was US$4.43, while the net costs were US$3.56 for composite resin and US$4.87 for ART/HVGIC. (These are 2010 prices adjusted for inflation in China and subsequently converted to 2012 US dollars).

In examining the studies in the contexts of the Chinese and Brazilian economies, there are differences in the two economies which affect costs. These include factors like personnel salaries and which inputs (e.g., instruments, supply and equipment) are imported or manufactured in each country. The main cost driver in the Wuhan study was instruments and supplies, 56% of the composite resin costs and 79% of the ART/HVGIC costs, followed by personnel, 23% for composite resin and 15% for ART/HVGIC. Equipment for composite resin represented 12% whereas there was no cost for equipment for ART/HVGIC.

With respect to the Paranoá restoration study, ART/HVGIC performed well compared to amalgam which is the standard of care in Brazil and in many low- and middle-income countries. Because the study treatments were performed by pedodontists, this is a factor that can be modified. ART/HVGIC seems to be a viable alternative to amalgam.

The restoration study also illustrates how differences in costs will affect cost outcomes. Prices in Brazil tend to be lower compared to other countries in Latin America because many dental products are produced in that country. Dental care costs can also be expected to vary because of the difference in economies in the Latin American region. This can be seen in a study comparing amalgam and ART/HVGIC restorations placed by dentists in permanent

teeth in Panama, Ecuador and Uruguay where amalgam restoration costs ranged from US$7.77 to US$33.64 and ART/HVGIC restorations from US$3.64, to US$19.88 (5).

The results of the studies give individual practitioners and oral health program managers a sense of how the specific approaches compare within the countries where the research was conducted. They also produce information about trends that is generalizable beyond single countries. While these cost-effectiveness studies have substantial internal validity within their respective countries, structural differences among national economies, including the cost drivers in each economy, make it difficult to directly extrapolate the results to services in other countries. Thus, it is fair to say that the internal validity of the studies is substantially high, but their external validity is limited.

Recommendations

The challenges identified in the development and implementation of our costing and cost-effectiveness studies and in the interpretation and extrapolation of our findings from the study populations to the general population — helped to highlight areas of future research needs. One of the motivating factors for this PhD thesis was the paucity in economic evaluation research in oral health, compared to other health disciplines. Research into the costs and cost-effectiveness of oral health interventions is growing. More is required to produce a solid body of evidence that practitioners, oral health program managers and policymakers can refer to. The work done in this thesis points to a few areas where research should be pursued.

In the area of sealants, further cost-effectiveness research should be pursued for comparisons of ART/HVGIC to composite resins. In particular, this will be of value as newer formulations of both types of materials are becoming available on the market.

Cost-effectiveness research on supervised toothbrushing of cavitated dentine carious lesions should be conducted to explore different models under the combined supervision of the schools and the family health care teams. These models should evaluate how many visits are required to achieve a high level of efficacy in cleaning dentine cavities in primary teeth to make them plaque-free through supervised toothbrushing. Another important element, especially with respect to costs, is the the personnel teaching and supervising the children in terms

of number of days of supervision and personnel doing the supervision — community oral health promoters, teachers, and/or parents.

Research on the cost-effectiveness of ART/HVGIC restorations is an area that should be explored for the age group seen in the studies reported on in this thesis, ages 6-8, as well as for younger and older children.

The cost data generated in the studies reported here can be used with other data to model the costs benefits of different approaches to oral health care of children over the long term.

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Chapter 7

Summary

Summary

This PhD thesis investigated the costs and cost-effectiveness of key prevention and care measures for primary oral health care — prevention of cavitated dentine carious lesions through supervised toothbrushing with fluoride toothpaste, dental sealants, and restorations — targeting school age children. The prevention effectiveness studies evaluated in this PhD thesis were carried out as part of school-based community trials in Wuhan, Hubei Province, China and Paranoá, Brasilia, Brazil.

Chapter 1 describes the context of the work in this thesis in terms of the global burden of disease of dental caries for schoolchildren and adults and its economic implications. Dental caries affects large portions of the populations or specific population groups in low, middle and high-income countries around the world. Often access to oral health care is difficult and expensive, particularly burdening poorer populations. The studies in this PhD thesis focus on two middle income economies that have been developing rapidly over the last 20 years — China and Brazil — and, which have experienced large inequalities in both heath and income status. In efforts to counter wide health inequalities countries can seek to improve the availability of health care, in this case oral health care, through developing public health services and providing increased access to them. To do so they need information on the most effective and cost-efficient programs to reach larger portions of the populations. Economic evaluation can provide information about alternative interventions within the context of limited resources. This PhD represents an effort to enhance the capacity of the information available to decision makers in an effort t enhance their ability in making choices between alternative oral health primary care prevention intervention initiatives.

The caries prevention approaches reviewed in this chapter relate to the use of sealants to prevent caries development and restorations to prevent pain as well as stop continued progression of dentine caries. The traditional approach to dentistry has included the use of rotary instruments to restore cavitated dentine carious lesions with amalgam. In the latter part of the 20th century, composite resin sealants have targeted high-risk children. Around that time a less invasive approach emerged which uses hand instruments high-viscosity glass iono-

mer cements, atraumatic restorative treatment (ART). More recently, dentists are considering another prevention approach — whether or not to treat all cavitated dentine carious lesions in the deciduous teeth.

Chapter 2 reports on the methods and preliminary results of the cost-effectiveness study in Wuhan, China, evaluating the caries preventive capabilities of several sealant materials placed in the first permanent molars of 7- to 9-year-old children after 2 years. The cost-effectiveness study sought to determine the incremental cost-effectiveness of the sealants given their rates of survival. Sensitivity analyses evaluated the impact of the incidence of dentine caries lesions on the different sealant materials. Cost data collection methods were combined with a method to collect data on personnel time known as activity sampling. The main focus of the costing exercise, after two years, was the calculation of cost per sealant placed and the net cost per sealant, including the costs of adverse effects. In addition, the use of Disability Adjusted Life Years (DALYs) was introduced as a way of valuing the intervention in terms that are meaningful to policy-makers outside of China and a threshold was chosen. Although all materials showed high levels of effectiveness, the cost-effectiveness results after two years were inconclusive. Fewer dentine carious lesions developed in the LED thermocured HVGIC group but the cost of US$1,106 per caries lesion prevented per 1,000 LED thermocured HVGIC sealants placed was beyond the chosen threshold of US$226 per DALY (US dollars in 2010). Thus, this cost was deemed too expensive in terms of what many countries would be willing to pay, depending on their economic conditions and composite resin was deemed the more cost-effective option.

Chapter 3 presents the 4-year report of the cost-effectiveness of the materials evaluated in the Wuhan community trial, building on the methods established in the 2-year report of this study. The community trial tested two hypotheses: (i) glass-carbomer sealants have greater cumulative survival rates and caries-preventive effects than the high-viscosity glass-ionomer sealants, with and without heat application, or the composite resin, and (ii) the LED thermocured high-viscosity glass-ionomer sealant has greater cumulative survival rates and caries (cavitated dentine carious lesions) preventive effects than does high-viscosity

glass-ionomer sealant without heat application. The costs studied were: cost of sealing permanent molars; adverse event costs for restoring cavitated dentine carious lesions developing within 4 years in study data; and projection of 1,000 sealants per group.

The results at four years were congruent with trends in the outcomes seen in sensitivity analyses in the 2-year report. All sealant materials demonstrated a high level of effectiveness in preventing cavitated dentine caries lesions, with survival of the number of sealed pits and fissures being >94%. In this study, the glass-carbomer had the least favorable results and was the most expensive material, leading to the rejection of the first of the two hypotheses of the study. The second hypothesis was rejected because there was no significant difference observed between the LED thermocured high-viscosity glass-ionomer and the high-viscosity glass-ionomer groups. Application of threshold of US$226 per DALY applied to the resulting the costs for preventing one additional dentine carious lesion the for both the sample (US$105) and the projection (US$52) led to the conclusion that a school-based sealant project, such as this one, which costs less than US$226 per DALY, would fall within a range of what would be considered 'cost-effectiveness' and that government policy makers would consider feasible.

Chapter 4 describes a study that evaluated cavitated-dentine-carious-lesion-preventive capabilities of composite resin (CR) [reference group] and ART-high-viscosity glass-ionomer cement (HVGIC) sealants compared to supervised toothbrushing (STB) in high-risk first permanent molars over 3 years in a low-income suburb of Brasilia, Brazil. School children age 6-7 years. in 6 schools (2 per group) received CR and ART/HVGIC sealants or supervised toothbrushing daily for 180 days each school year. Data were collected prospectively and cost estimates were made for sample data and a projection of 1,000 sealants/STB high-risk permanent molars. Although STB had the best outcome, its high implementation cost (95% of the cost was for supervisors 180 days/school year) affected the results. ART/HVGIC compared to CR was cost-effective for the sample data (savings of US$37 per cavitated-dentine-carious-lesion prevented) while CR compared to ART/HVGIC was cost-effective for the projection (savings of US$17 per cavitated-dentine-carious-lesion prevented), and both were cost saving compared to STB. Two toothbrushing supervision scenarios were tested in sensitivity analyses with variations in caries incidence and number of supervision days. Under the two

new scenarios STB had lower costs and higher savings per cavitated-dentine-carious-lesion prevented than CR and ART/HVGIC. A major assumption is that both scenarios have the same high effectiveness rate experienced by STB under study conditions, however, they point to the value of further research on the benefits of adopting STB as a long-term venture in a general population of school children.

Chapter 5 explores the cost-effectiveness and implications of performing amalgam and ART/high-viscosity glass-ionomer cement (HVGIC) restorations over 3 years. Although on a trajectory to be phased out, amalgam remains the standard of care in many countries, thus, it is useful to understand, especially in resource-strapped countries, the cost implications of switching to alternative materials. Cost data were collected prospectively from a government program perspective. Cost estimates were developed for the study sample and a projection of 1,000 single- and 1,000 multiple-surface restorations per group. Probabilistic sensitivity analysis was conducted in TreeAge Pro. Results were mixed. For single-surface restorations, ART/HVGIC will cost US$51 per failure prevented, while for multiple-surface restorations, ART/HVGIC was cost-effective with a savings of US$11 compared to amalgam. Probabilistic sensitivity analysis (Monte Carlo simulation) predicted amalgam would be cost-effective 49.2% of the time compared to HVGIC at 50.6% of the time. Personnel accounted for more than half the cost burden for both methods; instruments and supplies accounted for about one third. The per restoration cost to replace amalgam with HVGIC ranges from US$1 to a savings of US$0.84. Replacing amalgam with a high-viscosity glass-ionomer as part of the ART method comes at a minimal increase in cost for governments. Increasing the number of restorations seems to diminish the cost burden. ART/HVGIC could be considered a viable alternative to amalgam in primary teeth.

Chapter 8

Samenvatting

Samenvatting

Dit proefschrift onderzocht de kosten en de kosteneffectiviteit van preventieve en restauratieve behandelingen bij schoolgaande kinderen. Onderzocht werden behandelingen die gecaviteerde carieuze dentinelaesies voorkómen in putten en fissuren van blijvende kiezen met een hoog cariësrisico door het onder supervisie poetsen met fluoride tandpasta en door het verzegelen ervan; en het stoppen van het cariësproces in dentine caviteiten door het plaatsen van restauraties en door het schoon poetsen van caviteiten met tandenborstel en fluoride tandpasta in tijdelijke gebitselementen. De onderzoeken waren onderdeel van twee klinische onderzoeken die, respectievelijk, in Wuhan, Hubei, China en in Paranoá, Brasilia, Brazilië waren uitgevoerd.

Hoofdstuk 1 beschrijft de context van het proefschrift in termen van algemene last die schoolkinderen en volwassenen door tandcariës ervaren en de economische implicaties daarvan. Tandcariës komt in grote delen van de wereldbevolking voor en in specifieke groepen in lage, midden- en hoge inkomenslanden. In veel landen is toegang tot mondzorg moeilijk en duur, met name in armere landen en bevolkingsgroepen. De studies in dit proefschrift richten zich op twee middeninkomenseconomieën die zich de afgelopen 20 jaar snel hebben ontwikkeld — China en Brazilië — en die grote ongelijkheden in zowel gezondheid als inkomensstatus laten zien. In het tegengaan van grote ongelijkheden op gezondheidsgebied kunnen landen proberen de beschikbaarheid van de zorg te verbeteren, in dit geval mondzorg, door het opzetten van publieke gezondheidsdiensten en het bieden van betere toegang tot bestaande diensten. Hiervoor hebben landen informatie nodig over de meest effectieve en kostenefficiënte zorgprogramma's om grotere delen van de bevolking te bereiken. Economische evaluatie kan informatie verschaffen over alternatieve interventies in de context van beperkt aanwezige middelen. Dit proefschrift is een poging om de beschikbare informatie voor besluitvormers te vergroten en zodoende hun vermogen te vermeerderen om keuzes te maken tussen bestaande en alternatieve initiatieven voor preventie en curatie van tandcariës.

De cariëspreventieve maatregelen die in dit hoofdstuk worden besproken, hebben betrekking op het gebruik van verzegelingen om cariësontwikkeling te voorkómen en op restauraties

om pijn en progressie van carieuze dentinelaesies te stoppen. In veel landen maakt de traditionele behandeling gebruik van roterende instrumenten en amalgaam om gecaviteerde carieuze dentinelaesies te herstellen. In het laatste deel van de 20ste eeuw werden kunststofverzegelingen gebruikt om kinderen met een hoog cariësrisico te behandelen. Rond die tijd ontstond ook een laag invasieve behandelmethode die gebruik maakt van handinstrumenten en hooggevuld glasionomeer cementen (HVGIC) en verzegelingen en restauraties produceert; de atraumatische restorative treatment (ART). Meer recent overwegen tandartsen zelfs een behandelaanpak die restaureren van gecaviteerde carieuze dentine laesies in de melkelementen overbodig maakt door het schoonhouden ervan.

In Hoofdstuk 2 worden de methoden en voorlopige resultaten van het kosteneffectiviteitsonderzoek van verschillende verzegelingsmaterialen, geplaatst in de eerste blijvende kiezen van 7- tot 9-jarige kinderen uit Wuhan, na 2 jaar vermeld. Het kosteneffectiviteitsonderzoek had tot doel om de incrementele kosteneffectiviteit van de verzegelingen te bepalen aan de hand van hun overlevingspercentages. Gevoeligheidsanalysen evalueerden de invloed van de incidentie van gecaviteerde carieuze dentinelaesies voor de verschillende typen verzegelingsmaterialen. Methoden voor het verzamelen van de kosten werden gecombineerd met een methode om gegevens te verzamelen over welke handeling het personeel deed in een bepaalde tijdsperiode en die bekend staat als activiteitensteekproef. De belangrijkste focus van deze activiteit was het berekenen van de kosten per aangebrachte verzegeling en de netto kosten per verzegeling, inclusief de kosten van schadelijke effecten in de tijd. Daarnaast werd het gebruik van Disability Adjusted Life Years (DALY's) geïntroduceerd als een manier om de interventie te waarderen in termen die relevant zijn voor beleidsmakers buiten China, en werd er gekozen voor het instellen van een drempelwaarde. Alle type verzegelingen vertoonden een hoge mate van effectiviteit en de kosteneffectiviteitsresultaten na 2 jaar waren niet doorslaggevend. Het geringste aantal carieuze dentinelaesies ontwikkelde zich in de groep met ART/HVGIC verzegelingen waaraan tijdens de uitharding warmte was toegevoegd (LED-thermocured). Echter, de kosten van US$ 1.106,- om één carieuze dentinelaesie per 1000 geplaatste LED-thermocured ART/HVGIC verzegelingen te voorkómen viel buiten de gekozen drempelwaarde van US$ 226,- per DALY (US dollars in 2010). Deze kosten werden dus te hoog beschouwd in

termen van wat veel landen bereid zouden zijn te betalen, afhankelijk van hun economische toestand natuurlijk, en daarom werd de kunstharsverzegeling na 2 jaar onderzoek als de meer kosteneffectieve optie beschouwd.

In Hoofdstuk 3 worden de resultaten van het 4-jaars kosteneffectiviteitsonderzoek naar het verzegelen van putten en fissuren gepresenteerd dat voortbouwt op de methoden die in de 2-jaar publicatie staan beschreven. Het klinische onderzoek testte twee hypothesen: (i) glascarbomeerverzegelingen hebben een hoger cumulatieve overlevingspercentage en cariëspreventief effect dan verzegelingen van hooggevuld glasionomeer, met en zonder warmte toevoeging, en die van kunsthars, en (ii) de verzegelingen van hooggevuld glasionomeer met warmte toevoeging (LED-thermocured) hebben een hogere cumulatieve overlevingspercentage en cariës (gecaviteerde dentinelaesie) preventief effect dan verzegelingen van hooggevuld glasionomeer zonder toevoegde warmte. Kosten voor het verzegelen van blijvende molaren, voor het plaatsten van een restauratie in dentinecaviteiten, die zich gedurende de 4 jaar ontwikkelden, en kosten voor de projectie van 1.000 verzegelingen per behandelgroep bepaalden de post kosten.

De 4-jaars resultaten kwamen overeen met die uit de gevoeligheidsanalysen die in de 2-jaars publicatie staan vermeld. Alle type verzegelingen vertoonden een hoge mate van effectiviteit in het voorkómen van gecaviteerde carieuze dentinelaesies (>94%). Glascarbomeer had het minst gunstige resultaat en was ook het duurste. Daardoor werd de eerste van de twee hypothesen afgewezen. De tweede hypothese werd afgewezen omdat er geen significant verschil was waargenomen tussen verzegelingen van hooggevuld glasionomeer dat verwarmd en niet verwarmd was. Indien de drempelwaarde van US$ 226,- per DALY werd toegepast bleek dat de kosten voor het voorkómen van één extra carieuze dentinelaesie voor zowel de steekproef (US$ 105,-) als de projectie van 1000 verzegelingen (US$ 52,-) tot de conclusie leidde dat een schoolzorgprogramma, zoals het onderhavige dat binnen de US$ 226,- per DAILY valt, als ‘kosteneffectiviteit’ kan worden beschouwd en dat beleidsmakers van een overheid het haalbaar zouden achten.

Hoofdstuk 4 beschrijft een studie die het voorkómen van gecaviteerde carieuze dentinelaesies vergelijkt tussen het verzegelen van eerste blijvende kiezen met een hoog cariësrisico door kunsthars (CR) [referentiegroep] en hooggevuld glasionomeer cement (HVGIC), aangebracht volgens de ART methode (ART/HVGIC), en het poetsen van de kiezen met fluoride tandpasta (STB). Het onderzoek duurde 3 jaar en werd uitgevoerd bij 6-7 jaar oude schoolkinderen van 6 scholen uit een buitenwijk van Brasilia, Brazilië met een laag inkomen status. De kinderen poetsen zelf hun tanden en kiezen (STB) gedurende 180 dagen per schooljaar, maar deden dat wel onder toezicht van een medewerker. Onderzoeksgegevens werden prospectief verzameld en kostenramingen werden opgesteld voor de studie zelf en voor een projectie van 1000 verzegelingen per groep en voor de STB. Hoewel STB de beste uitkomst had, beïnvloedden de hoge uitvoeringskosten de resultaten (95% van de kosten (salaris) kwam voor rekening van de medewerker). Vergeleken met de CR verzegeling was de ART/HVGIC verzegeling kosteneffectief voor de studie (besparing van US$ 37,- per voorkómen van één gecaviteerde carieuze dentinelaesie) terwijl de CR verzegeling dat was voor de projectie (besparing van US$ 17,-). Beide verzegelingen waren kostenbesparend in vergelijking met STB. Gezien de hoge salariskosten van de medewerker werden twee scenario's voor de STB groep getest in gevoeligheidsanalysen met variaties in de incidentie van gecaviteerde carieuze dentinelaesie en het aantal supervisiedagen. Onder de twee nieuwe scenario's had de STB lagere kosten en hogere besparingen in het voorkómen van gecaviteerde carieuze dentinelaesie dan CR en ART/HVGIC verzegelingen. Een belangrijke aanname in beide scenario's was dat dezelfde hoge effectiviteitsgraad wordt bereikt als voor STB in de huidige studie. De uitkomst van de scenario's wijzen op het belang van verder onderzoek naar het gebruik van STB als een lange termijn behandeling bij schoolkinderen.

In Hoofdstuk 5 worden de kosten en implicaties van het uitvoeren van amalgaam en ART/HVGIC restauraties over een periode van 3 jaar onderzocht. Hoewel amalgaam op termijn afgeschaft wordt, blijft het vooralsnog het standaardmateriaal voor restauraties in veel landen. Het is dus nuttig om, vooral in landen met beperkte middelen, de kostenimplicaties van het overstappen van amalgaam naar alternatieve restauratiematerialen te meten. Gegevens over kosten werden prospectief verzameld vanuit het perspectief van een overheid-

sprogramma. Kostenramingen werden ontwikkeld voor de studie en een projectie van 1.000 eenen 1.000 meervlaks restauraties voor beide behandelgroepen. De effectiviteit van beide behandelmethoden was vergelijkbaar. Het aanbrengen van ART/HVGIC restauraties duurde langer per eenheid van toepassing en de kosten ervan waren marginaal hoger dan die van restauraties met amalgaam. Dat gold voor zowel de eenals meervlaks restauraties. Het kostenverschil daalde met het toenemen van het aantal behandelingen in de projectie. Personeel nam voor beide behandelmethoden meer dan de helft van de kosten voor zijn rekening; instrumenten en equipment waren goed voor ongeveer eenderde van de kosten. Het vervangen van amalgaam door een hooggevuld glasionomeer als onderdeel van de ART methode leidt tot een minimale stijging van de kosten voor overheden. Toename van het aantal restauraties lijkt de kosten te verminderen. De mogelijkheid om invloed uit te oefenen op de personeelskosten in combinatie met de mogelijkheid om restauraties volgens de ART methode buiten de tandheelkundige kliniek toe te passen, benadrukt ART/HVGIC als een waardevol alternatief voor de traditionele restauratieve behandeling met amalgaam. Het kan ertoe leiden dat de toegang tot tandheelkundige zorg voor grotere aantallen kinderen verbetert, vooral in gebieden waar nu weinig zorg wordt verstrekt.

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Daniel Hawes and Anne Haddix, gave me advice for responding to reviewers' comments. Karyn Pomerantz proofread the Wuhan articles before they were published in journals; Joy Doty proofread part of this manuscript. Betsy Berlin made it look like a book!

Jeanne Goldman, my sister, undertook the load of carrying on with the daily management of matters relating our late parents' home in Puerto Rico, allowing me to dedicate more

of my personal time to pursuing my PhD goal. My cousins Susan Lekanides and Lili Bohan, welcomed me into their home in New York City while I worked with Jo in the summer of 2016.

My late parents, Max and Vicki Goldman, showered both Jeanne and myself with encouragement and unconditional love. They placed great value on education and were present for all of my graduations. Though they will not be with me now, they accompany me in spirit.

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Curriculum Vitae

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Education and Training

New York University, NY, B.A. (1981), History, Journalism, and French

The Johns Hopkins Paul H. Nitze School of Advanced International Studies, Washington, D.C., M.A. (1983), Latin American Studies and Economics

The George Washington University, Washington, D.C., M.P.H. (1996)

Radboud University, Nijmegen, Netherlands, Doctoral Candidate, International Oral Health Unit

Professional Employment

Director of Education Programs, Lecturer (1998 to present), Milken Institute of Public Health, The George Washington University. Mentor MPH and MS PHMEID students through their practice requirements, including orientation, identification of sites and preceptors, and advising. Co-Investigator and Coordinator of the project for Ascertainment of Estimated Excess Mortality from Hurricane Maria in Puerto Rico. Responsibilities include teaching, research and administrative support to PhD in Epidemiology program. Research: a) Economic evaluation of public health prevention programs with respect to neglected tropical diseases and oral health; b) CTSI Team Science Core; c) Economic burden of malaria cases imported from Hispaniola to other non-endemic countries in the Western Hemisphere; d) Teratogenic effects of aflatoxins and fumonisins in Guatemala; e) Mortality certification in disasters.

Consultant (2002 to Present)

Also, please see grants and contracts, and public health practice activities.

Project Coordinator (1995–1998), GW International Health Care Consulting Group. Development and coordination of international projects. Project Coordinator: Instituto Nacional de Servicios Sociales Para Jubilados y Pensionados, Argentina (Nacional Social Services Institute for Retirees and Pensioners). Advised the Director; preparation of educational materials and teaching (practical applications of epidemiological concepts and information); participated in research and proposal writing.

Project coordinator (1995–1997), GWUMC Department of Medicine. Participated in development and coordination for projects in Brazil and Argentina. Coordinated and participated in the development of research proposal for cardiovascular research in a U.S. Latino population, submitted to NIH. Faculty affairs coordinator.

Research assistant and project coordinator (1993–1995), Pan American Health Organization, Washington, D.C. Regional AIDS/STD Program, Division of Communicable Diseases and Prevention Control. Assisted in the preparation and editing of the PAHO 1992 AIDS,

HIV, & STD Surveillance Report for the Americas. Participated in the development and implementation of a protocol to validate syndromic management of sexually transmitted diseases in Peru; including two site visits to Lima, Peru for project preparation and wrap up. Participation in the analysis of country assessment reports on congenital syphilis and the preparation of a PAHO concept document calling for a regional plan for the elimination of congenital syphilis.

Research assistant and project coordinator (1992–1993), The GW Center for International Health, Washington, D.C. Participated in the coordination of the Center's 1992 International Forum on Health and Development in June. Collaborated in researching, writing and editing The Health-Development Link, published in1994. Other Center activities included participation in developing publications, receiving foreign visitors, writing, and editing.

Program associate and later director (1989–1992), Health Services Program, Pan American Development Foundation, Washington, D.C. The program transferred donated medical resources to hundreds of health care related non-profit, public, and educational institutions in Latin America. Coordinated the activities of a staff of three; defined and implemented program policy; designed training programs for health professionals. Prepared and administered $300,000 program budget.

Legislative tracking and research (1984–1989), Office of United States Senator Alan Cranston, Washington, D.C. Advisor to the Senator, a member of the Foreign Relations Committee, on issues including Latin America, U.S. defense policy, the Middle East, space exploration and satellites. Drafted speeches, tracked legislation, and responded to constituent inquiries. Duties evolved from those of a legislative correspondent to responsibilities that included exploring and evaluating policies, programs and proposals.

Grants Concluded

Health Disparities Research (2005–2007), National Minority Quality Forum,

Yearly Direct Cost: 20% FTE

Research exploring the economic implications of health disparities with respect to certain diseases such as diabetes, at the local level.

Elimination of Lymphatic Filariasis Grant (2002–2005), Sub-contract with Emory University Lymphatic Filariasis Support Center (ELFSC), Atlanta, GA. The ELFSC is now located at the Task Force for Global Health, Decatur, GA.

Direct Cost: 30% FTE

Researcher, member of ELFSC team developing the protocol and data collection instruments for a seven-country cost analysis. Provided technical support to country research teams in Philippines, Egypt, Ghana, Burkina Faso, and Tanzania. Reviewed and analyzed country data and worked on drafting a manuscript.

Publications

Articles in Refereed Journals

Goldman AS, de Amorim RG, Frencken JE, Leal SC. Replacing amalgam with a high-viscosity glass-ionomer in restoring primary teeth: A cost-effectiveness study in Brasilia, Brazil. *J Dent* 2018; 70: 80–86.

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Kassler, WJ, Dillon, BA, Haley, C, Jones, W, Goldman, A. On site, rapid HIV testing with same-day results and counseling. *AIDS* 1997, 11: 1045–1051.

Non-Peer Reviewed Reports

Stoto MA, Goldman, AS. Preventing Perinatal Transmission of HIV, DRU 3071-IOM, Prepared for the IOM Committee on Improving Birth Outcomes in Developing Countries. Rand Corporation: Arlington, VA, October, 2003. This manuscript was written for the Institute of Medicine (IOM) and appeared as a chapter entitled Maternal to child transmission of HIV, in the report, Improving Birth Outcomes: meeting the challenge in the developing world. Washington (DC): Institute of Medicine; Nov. 2003.

Books

Rodriguez-García R., Goldman A. The Health Development Link. Washington, D.C.: Pan American Health Organization (PAHO/WHO); 1994.

University Service

a) Committee service — Department of Epidemiology and Biostatistics Curriculum Committee; SPHHS Practicum Directors' Committee: Participated with the Associate Dean for Research and other Practicum Directors in the design of the SPHHS Practicum Website and continue to meet with the SPHHS Practicum Coordinator and other PDs on a regular basis.

b) Student Affairs Advisory Board, representative for the Department of Epidemiology and Biostatistics

c) Faculty Liaison, assisting the deans in the organization and implementation of the CEPH self-study process for the Public Health Program in 1998 (Dean: Richard Riegelman, MD, PhD, MPH) and the SPHHS in 2003 (Dean; Richard Southby, PhD).

Editorial Peer Review Activities

Reviewed two articles, one for the American Journal of Tropical Medicine and Hygiene, and two for Public Library of Science Neglected Tropical Diseases (PLoS NTDs).

Teaching/Learning Portfolio

PubH 6261 Epidemiology Biostatistics Skills Building Seminar — Member of team for course development and organization and lecturer, 2007–2016.

Small group leader for: PubH 6003 Principles and Practice of Epidemiology, Fall 2011.

Nutritional Epidemiology PubH 6099, Fall 2012 and 2013; and Study Design in Epidemiology PubH 6247, Spring 2013.

Taught PubH 239, study design for non-epidemiology students, 2003.

Distance Learning Instructor for the Epidemiology Department for the GW-MEDUNSA (South Africa) – Hebrew University (Israel) Community Oriented Public Health Certificate Program; two courses on how to read the health literature and on cost-effectiveness evaluation and decision making in health. 1997–2000.

Public Health Practice Portfolio (Consultations)

Cost analyst (2010–2011), Optimization of chemotherapy for control and elimination of onchocerciasis and lymphatic filariasis (DOLF), University of Washington, St. Louis, MO (Dr. Gary Weil, PI). Research to model and compare the costs of annual vs. semiannual mass chemotherapy to prevent lymphatic filariasis in India and West Africa. Design and implementation of a cost analysis study of community trials comparing annual vs semiannual mass chemotherapy in countries in Africa and South Asia-Pacific, including Indonesia, Papua New Guinea and Liberia.

Cost analyst (2014–2015), The Carter Center. Researched the literature and obtained data for the development of a model to estimate the burden of disease and lymphatic filariasis and malaria in Hispaniola and estimated costs of future efforts to eliminate these diseases.

Cost consultant (2011), Fit for School, Inc., Manila, The Republic of the Philippines. Designed a study to estimate the cost of the Essential Health Care Programme (EHCP), a school health program implemented by the Philippine Department of Education (DepED). This program consists of three components, daily ß∑ing and hand washing, and twice annual deworming, which currently reaches more than 1,200,000 children. Produced Report for the funding agency, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), a corporation owned by the German government that supports international cooperation for sustainable development.

Cost consultant (2008–2010), Research Triangle International, Inc., United States Neglected Tropical Disease Program, Washington, DC. Development and supervision of a study to cost the integrated program in Haiti for delivering medications for the prevention of lymphatic fila-

riasis and soil transmitted helminth infections. Participated as one of the developers of a budgeting instrument that combines cost and epidemiologic information to assist countries in the development of integrated NTD programs. This tool has evolved into the Tool for Integrated Planning and Costing (TIPAC).

Consultant (2007–2008), World Bank Institute, Health and HIV/AIDS Team, Washington, D.C. Managed the development of an annotated bibliography on poverty and inequality, particularly as their impact on health.

Doctoral Studies Research

Cost-effectiveness of sealants in Chinese children. The purpose of this study which began in 2008 is to evaluate the cost effectiveness of glass ionomer and composite resin dental sealants and approaches to their application in preventing the development of carious lesions in the first permanent molars of Chinese school children after four years.
Role: Co-investigator for the cost effectiveness analysis (PhD Candidate, Department of Oral Global Health, Radboud University, Nijmegen, Netherlands)

Cost-effectiveness of basic oral care approaches in Brazilian caries-active children. This study, which began in 2009, seeks to evaluate approaches to treatment of caries in children to determine the most cost-effective treatment that ensures natural exfoliation of primary teeth in caries-active children, prevents caries lesions in first permanent molars, keeps restorative treatment to a minimum and stimulates children to maintain good oral care practices.
Role: Co-investigator for the cost effectiveness analysis (PhD Candidate, Department of Oral Global Health, Radboud University, Nijmegen, Netherlands)

Professional Service Activities

WHO Task Force Meeting on Measuring Impact of Preventive Chemotherapy Interventions Neglected Tropical Diseases. Participated in the 2012 meeting to constitute the task force participating as a member of its socioeconomics and poverty sub-committee.

Member of committee set up by the Infectious Diseases Development Group of the Gates Foundation Global Health program to design a protocol and instrument for costing the delivery of prevention programs in the neglected tropical disease (NTD) integration studies funded by the Bill and Melinda Gates Foundation (2007–2010).

Voluntary Service Activities

Chair, Architectural Review Committee, Gateway Georgetown Condominium Association (2006–2016)

Board member, Gateway Georgetown Condominium Association (2000–2006)

Past board member (1991–96) and President (1996–98), Johns Hopkins University Alumni Association Washington Metropolitan Area Chapter

Volunteer at La Clínica del Pueblo (1994–95)

Volunteer at AYUDA Legal Services Clinic (1990–91)

Affiliations

Member, Association of Tropical Medicine and Hygiene

Personal

Languages: English, Spanish, French, Portuguese